Review of the Human Fertilisation and Embryology Act

A Public Consultation

Department of Health 2005

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Foreword

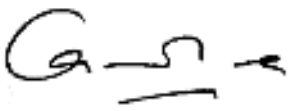
The United Kingdom is a world leader in human reproductive technologies. The first child conceived through *in vitro* fertilisation was born in this country in 1978. Today more than 8,000 children are born here through IVF every year. UK clinicians and scientists continue to lead the world in developing new treatments to alleviate infertility.

The UK is also a pioneer of legislative and regulatory oversight of reproductive technologies. The *Human Fertilisation and Embryology Act 1990* (the HFE Act) was a landmark piece of legislation. It followed extensive consideration of the social, ethical and legal implications of new technologies that enabled, for the first time, observation and manipulation of the earliest stages of human development. And it set up the Human Fertilisation and Embryology Authority – the first regulatory body of its type in the world.

The HFE Act has stood the test of time well, and is a tribute to the foresight of its creators. It was drawn up based on proposals from an expert committee of inquiry (the Warnock Committee), and full public consultation. The Act and the regulatory system it established have instilled public confidence in the safe and ethical use of assisted reproduction technology subject to appropriate safeguards. However, it was never expected that the Act would remain forever unchanged in this area of fast-moving science. The Government announced in 2004 that it intended to review the provisions of the HFE Act, including holding a public consultation exercise in 2005.

This consultation document seeks views on whether and how the law might be updated given the rise of new technologies, changes in societal attitudes, international developments, and the need to ensure effective regulation. It takes full account of the House of Commons Science and Technology Committee's recent review of human reproductive technologies and the law, for which we thank the Committee.

The topics covered raise many complex and often fundamental ethical issues, on which views may diverge widely. There are important matters of reproductive freedom and responsibility, patient safety, public accountability and professional autonomy, and how best to safeguard the welfare of the children. We very much hope that you will take the time to respond to this consultation and help us tackle these vital questions.



Caroline Flint MP
Parliamentary Under Secretary of State for Public Health

Section One – Introduction and how to respond

1.1 Parliament passed the *Human Fertilisation and Embryology Act* fifteen years ago[1]. It represented the culmination of debates carried on over the previous two decades which had seen the birth of the first child from the technique of *in vitro* fertilisation (in July 1978), and the opening up of new horizons in assisted conception and the science of embryology. A Committee of Inquiry, chaired by Dame (now Baroness) Mary Warnock, had produced the "Warnock report" of 1984, with recommendations for a scheme of regulation[2]. Extensive public consultation, which included Government 'green' and 'white' papers, led to firm legislative proposals and, after vigorous parliamentary debate, to the framing of the HFE Act.

1.2 The HFE Act itself was evidence of a fundamental consensus – namely that there must be *some* principles, barriers or limits to govern behaviour in this area. Therefore the law, in setting out what is legally permissible, defined the minimum requirements for acceptable practices. However, as the Warnock report pointed out, in a pluralistic and multi-faith society there will not be universal agreement on where the barriers and limits should be placed. Individually we might all wish that the limits were placed elsewhere. Nevertheless, the law reflected an underlying will to find common ground.

1.3 The Government believes that the HFE Act has performed well and largely continues to do so. It has enabled science and medicine to flourish within the bounds agreed by Parliament, and its fundamental elements and principles have been studied closely around the world. But any cutting-edge legislation, no matter how successful, needs at some stage to be reviewed and any necessary readjustments made to ensure that it continues to be effective. Although the Act contains much that is forward-looking, it operates within an inherently fast-moving area of scientific development, sometimes leading and sometimes following behind broader social changes.

1.4 The Government's aim, in reviewing the Act, is to ensure that the law remains effective and fit for purpose in the early 21st century. This consultation is part of a process of re-establishing a framework that is broadly acceptable to society.

1 The Human Fertilisation and Embryology Act 1990 (c. 37). Available online at www.hmso.gov.uk/acts/acts1990/Ukpga_19900037_en_1.htm, or published by The Stationery Office Limited, ISBN 0105437905. An outline of the Act is provided in Annex A of this document.

2 Report of the Committee of Inquiry into Human Fertilisation and Embryology, Cm 9314, July 1984, ISBN 0101931409. Referred to hereafter as the Warnock report.

Why is the Government reviewing the law?

1.5 An outline of the Human Fertilisation and Embryology Act is provided at Annex A.

1.6 The Government decided in 2004 that a review of the HFE Act was timely and desirable in the light of a number of factors. These included:

- the development of new procedures and technologies in assisted reproduction, such as techniques which would enable sperm to be selected for the purpose of creating a child of a particular sex
- international developments in the standards that clinics have to meet
- possible changes in public perceptions and attitudes on complex ethical issues
- the need to ensure the continued effectiveness of regulation.

1.7 A further factor was that although the HFE Act has stood up well to legal challenges in the courts, it is clearly better if any uncertainty and scope for challenge is reduced in the first place. The Department of Health's interpretation of the Act has been supported by the courts to date, but the Government believes that an important part of this review is the need to ensure that the law is as clear as possible. The Government's decision to review the HFE Act was announced on 21 January 2004.

The scope of the Government's review

1.8 Specific aspects of the law on assisted reproduction and embryo research have often been scrutinised in parliamentary debates and inquiries. However, there has not previously been an opportunity for the public to comment formally to Government on the continuing appropriateness and effectiveness of the HFE Act. Responses to this public consultation will inform any proposals for changes to update the law that the Government may bring forward, as necessary, when parliamentary time allows.

1.9 The Government's framing of this review has benefited from the timely and informative inquiry into human reproductive technologies and the law by the House of Commons Science and Technology Committee. The Committee gathered a large amount of written evidence and interviewed a wide range of witnesses during a yearlong inquiry, and made 104 recommendations in a report published on 24 March 2005. The Committee's report is available online at www.parliament.uk or from The Stationery Office[3].

3 House of Commons Science and Technology Committee Fifth Report of Session 2004-05, *Human Reproductive Technologies and the Law*, Volume I, HC 7-I, ISBN 0 215 02323 4. See also Volume II, Oral and Written Evidence, HC 7-II, ISBN 0 215 02315 3, and Eighth Special Report of Session 2004-05, HC 491.

1.10 While many of the Committee's recommendations call for changes to the law, the Committee considered that the basic foundations of the HFE Act remain sound. This included the approach taken in the Warnock report to the status of the human embryo, and the need for a dedicated regulator. The Government's formal response to the Committee's recommendations is published separately. On many of the matters raised by the Committee, the Government has agreed to seek wider public views through this consultation.

1.11 The law has not, however, stood still since 1990. There have been several important developments, such as the changes made in 2001 to extend the purposes for which embryo research can be licensed to include "increasing knowledge about the development of embryos", "increasing knowledge about serious disease", and "enabling any such knowledge to be applied in developing treatments for serious disease". This change opened the door to embryonic stem cell research which has great potential to lead to new treatments for diseases such as diabetes, heart disease and Parkinson's. Also in 2001, Parliament passed the *Human Reproductive Cloning Act* to outlaw any attempt to create a child through any process other than fertilisation using sperm and egg. This ruled out the possibility of a child being conceived by the same technology used to create 'Dolly' the sheep.

1.12 Another important change took place in 2004 when Parliament agreed that donor-conceived children will be able to access the identity of their sperm, egg or embryo donor on reaching the age of 18, where the donor registered from 1 April 2005.

1.13 The Government does not intend that the review of the HFE Act will open up those fundamental aspects of the legislation which are widely accepted in our society or which have been recently debated and conclusively resolved in Parliament. These include the creation and use of embryos for research, the prohibition on human reproductive cloning, and the removal of donor anonymity.

The European Directive on Tissues and Cells (the EU Tissue Directive)

1.14 The context for the Government's review of the HFE Act includes developments in international law and standards. On 31 March 2004, the European Parliament and the Council of the European Union passed Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

1.15 The Directive will set common standards of quality and safety for human tissues and cells intended for human application including reproductive tissues and cells. Implementation of the Directive will require changes to UK legislation independently of the Government's review of the HFE Act. The Department of Health will therefore consult separately on the implementation of the Directive into UK law.

The Department of Health's review of Arm's Length Bodies

1.16 In 2004 the Department of Health undertook a review of its "arm's length bodies" – national organisations sponsored by the Department of Health undertaking executive functions – as part of a wider programme to improve efficiency and cut bureaucracy. The objective of the programme is to reduce the burden on the frontline and free up more resources for the delivery of services to patients, with a redistribution of at least £0.5 billion a year by the end of 2007/08. The conclusions of the review were published in July 2004 in the report *Reconfiguring the Department of Health's Arm's Length Bodies*,[4] including proposals to reduce the number of arm's length bodies from 38 to 20.

1.17 One of the conclusions of the review was the proposal to replace, by April 2008, the Human Fertilisation and Embryology Authority and the Human Tissue Authority with a single body with responsibilities across the range of human tissues and cells. More details are given in this consultation document on the proposed Regulatory Authority for Tissue and Embryos (RATE), and comments are welcome.

How to respond

1.18 Consultation responses should be sent **by Friday 25 November** to the Department of Health as follows. Queries should also be directed to the same addresses.

by e-mail: review-hfe-act@dh.gsi.gov.uk

by post: Christopher Cox
Department of Health
Room 651c, Skipton House
80 London Road
London SE1 6LH
Tel: 0207 972 6113
Fax: 0207 972 5076

4 Available at www.dh.gov.uk/PublicationsAndStatistics/fs/en or from the Department of Health publications orderline 08701 555 455, quoting document reference 40378.

1.19 The information you send to us may need to be passed to colleagues within the Department of Health and other Government Departments. It may also be published in a summary of responses to this consultation. We will assume that you are content for us to do this and if you are replying by e-mail, that your consent overrides any confidentiality disclaimer that is generated by your organisation's IT system, unless you specifically include a request to the contrary in the main text of your submission to us. The Department of Health is subject to the Freedom of Information Act 2000, and may therefore publish or otherwise make available your response within the terms of that Act.

Format of responses

1.20 It would greatly help us in analysing the responses if you could:

- respond by e-mail
- make clear which question you are responding to, preferably by filling in your responses after each question using the electronic response template available online at www.dh.gov.uk
- keep answers brief and focussed.

1.21 It would also be helpful if representative groups could provide a summary of the people and organisations they represent, and the methodology used to obtain their members' views.

The Cabinet Office Code of Practice on Consultation

1.22 All UK written public consultations by Government departments and agencies are bound by the Cabinet Office Code of Practice on Consultation[5] and the criteria contained within it, which are:

- consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy
- be clear about what your proposals are, who may be affected, what questions are being asked and the time-scale for responses
- ensure that your consultation is clear, concise and widely accessible
- give feedback regarding the responses received and how the consultation process influenced the policy

5 The full text of the code is available on the Cabinet Office website at www.cabinet-office.gov.uk/regulation/consultation/code.htm

- monitor your department's effectiveness at consultation, including through the use of a designated consultation co-ordinator
- ensure your consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment if appropriate.

1.23 Respondents are invited to comment on the extent to which the criteria have been adhered to in this consultation process, and to suggest ways of further improving the consultation process.

1.24 The Cabinet Office is committed to reviewing the effectiveness of the code. Feedback *on the consultation code of practice* is welcome to:

Consultations Co-ordinator
Regulatory Impact Unit
Cabinet Office
5th Floor, Kirkland House
22 Whitehall
London SW1A 2WH
Tel: 0207 276 6275
E-mail: consultation.policy@cabinet-office.x.gsi.gov.uk

Section Two – The model and scope of regulation

2.1 Human reproductive technologies raise many profound issues and questions which go to the heart of our existence. These technologies may be used to benefit people individually, or for the benefit of society as a whole, and similarly the questions raised may concern people both individually and collectively. The issue is then to what extent society should make rules and regulations in this area, what those rules should say, and how they should be decided.

Why regulate human fertilisation and embryology?

2.2 The birth of Louise Brown, the world's first "test tube baby", confirmed a new technical ability to separate the process of conception into its constituent parts. In particular, the technique of *in vitro* fertilisation enabled, for the first time, human embryos to be created outside the body. This development brought the hope of alleviating infertility to a wider range of people than had previously been possible – a hope which has now been realised by many thousands of couples – via the intervention of highly skilled clinicians and embryologists, including through publicly funded services. It also opened up new possibilities to observe, select, test, and potentially to control and modify the very earliest stages of human development.

2.3 Against this background of new and potential developments, the Warnock Committee, set up in 1982, was asked to consider what policies and safeguards should be applied, including consideration of the social, ethical and legal implications. The Committee discovered that a common factor linking these developments was the undase or anxiety which they generated in the public mind. Today, the use and further development of reproductive technologies continue to raise a range of complex social, ethical and legal issues on which views diverge widely and are very deeply held. Some of these developments were anticipated when the HFE Act was drawn up, and some were not.

2.4 Since 1990, techniques to screen and select specific embryos which are free of certain genetic disorders have become increasingly used, and in a handful of cases embryos have been selected in the hope of providing a tissue match that could help save the life of a seriously ill brother or sister. New techniques for the creation of embryos which do not involve fertilisation have been developed, and research suggests that the creation of sperm and eggs from other bodily cells may become feasible in the future.

2.5 There is, however, an argument that anxieties about emerging reproductive technologies have more to do with the novelty of those developments than with their nature in themselves. As the Warnock report put it, "events were moving faster than they could be assimilated". If so, it could be argued that as those new technologies become more familiar so anxieties about them may diminish. Another argument might be that anxieties in themselves do not justify extensive regulation, unless actual harm can be demonstrated.

2.6 Ultimately, the Government believes 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.

2.7 **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.**

2.8 However, it is possible to achieve this aim in different ways which may have a greater or lesser impact on the ability of medical treatments and scientific developments to advance and flourish. Similarly the nature of regulatory intervention may change over time as evidence about the risks of a technique, or public attitudes toward its acceptability, change. The Government is committed to following the principles of good regulation developed by the Better Regulation Taskforce. Those principles are proportionality, accountability, consistency, transparency, and targeting. Respondents may wish to consider the extent to which good regulation principles are followed in the Government's proposals.

How does the current model of regulation work?

2.9 The current scheme of regulation under the HFE Act comprises several elements and makes use of a range of regulatory checks and balances within a framework for which Parliament is ultimately responsible.

2.10 The HFE Act set up the Human Fertilisation and Embryology Authority (HFEA) as a statutory licensing authority. This was a novel development which for the first time made an area of medical practice subject to oversight by an independent body. The HFEA is responsible for assessing licence applications in accordance with the criteria laid down by Parliament, and has the power to grant licences only within those parameters. In simple terms, the HFEA licenses and monitors clinics carrying out IVF or donor insemination, the storage of sperm, eggs and embryos, and embryo research. As part of the licensing process, the HFEA is required to inspect the premises where the activity is to be carried on.

2.11 Parliament also set out conditions which apply to all licences granted by the HFEA, including requirements to maintain proper records, and to obtain the consent of persons participating in treatment or research. Another requirement is the duty of the person under whose supervision the activities authorised by a licence are carried on (known as the "person responsible") to ensure that suitable practices, staff and equipment are used.

2.12 A further element of the regulatory scheme is the duty placed on the HFEA to maintain a code of practice giving guidance about the proper conduct of licensed activities, and the proper discharge of the duties of persons responsible. The code needs to be approved by the Secretary of State for Health and must be laid before Parliament. A failure to observe the provisions of the code may be taken into account in the HFEA's decisions to vary or revoke a licence.

2.13 The Government believes that the regulatory model set out in the HFE Act has, in general, worked well and continues to do so. It has engendered public confidence in the ethical development and use of human reproductive technologies. It has helped ensure the safety and quality of infertility services for patients. It has allowed medical and scientific progress to flourish within appropriate safeguards. And it has achieved consistency across the country because regulation is carried out by a single national body.

2.14 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.

2.15 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.

2.16 The Government has announced its intention to create, by April 2008, the Regulatory Authority for Tissue and Embryos (RATE), to replace the Human Fertilisation and Embryology Authority and the Human Tissue Authority. RATE will be the single "competent authority" responsible for overseeing the requirements of the EU Tissue Directive. Section 10 gives further consideration to the proposed composition, remit and functions of RATE. The establishment of RATE will require primary legislation.

The scope of regulation

2.17 The scope of regulation is set by a relatively small number of prohibitions, permissions and associated definitions. Together these determine the activities which are banned, and those which may be permitted under licence. In reviewing the scope of the HFE Act, the issue is whether those limits are in the right places and whether the definitions remain fit for purpose. It may be argued either that they include too much – that there are some matters which should not be subject to regulation – or alternatively that they include too little and do not bring regulation to bear where it is needed. There are several specific points on which the Government is seeking views or has proposals on which it is seeking comments. These are discussed below.

Definition of "embryo"

2.18 The meaning of the term "embryo" is defined (in section 1 of the HFE Act) as "a live human embryo where fertilisation is complete" and this definition underpins several of the basic prohibitions in connection with embryos (in section 3 of the HFE Act). It is therefore one of the most basic elements of the law.

2.19 This definition has been challenged in the courts on the grounds that it does not appear to include embryos created by processes that do not involve fertilisation in the usual sense of the union of sperm and egg. For example, the technique of cell nuclear replacement (more commonly known as 'cloning') does not involve sperm in the creation of the embryo. The courts have to date taken a 'purposive' approach to interpretation of the law on this point. They have assumed that in drawing up this part of the Act, Parliament intended that it should apply to all human embryos however they were created. The House of Lords confirmed in 2003 that embryos created by cell nuclear replacement do come within the regulatory remit of the HFE Act and are therefore subject to the control of the HFEA.

2.20 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.

2.21 The Government, and the House of Commons Science and Technology Committee, recognise the difficulty of framing a definition of embryo based either on the potential of the embryo or the means of its creation which is sufficiently broad to take account of future technological developments.

2.22 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.

2.23 This would effectively follow the current position achieved by the Human Reproductive Cloning Act which prohibits the placing in a woman of an embryo created other than by fertilisation.

2.24 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, and therefore the starting point from which the protection of law should apply is at the stage when two cells have formed – generally at around 36 hours.

2.25 The Government is aware that criticism of this provision is largely based on the desire 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 Government believes that to remove eggs in the process of fertilisation from the scope of regulation could open up loopholes and uncertainty.

2.26 The Government therefore believes that the correct approach is to consider the legitimacy of particular activities for embryo research or therapy rather than to remove eggs in the process of fertilisation from the definition of embryo. Embryo research is the subject of a later section in this consultation document.

2.27 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.

2.28 Consideration is given in section 9 to the appropriate legal controls on embryos containing human and animal genetic material (known as chimeras or hybrids), and in sections 5 and 9 to the possibility of forms of genetic modification of human gametes and embryos.

Definition of gametes, eggs, sperm

2.29 The HFE Act does not define the terms "gametes", "eggs" or "sperm" other than to say that, unless otherwise stated, they refer to live human gametes, eggs and sperm.[6] However, new developments in technology may make the creation of artificial

6 In this consultation document, the term "gametes" is used to refer to human sperm and eggs unless stated otherwise.

gametes – cells which are capable of performing the same functions as naturally produced sperm and eggs – a realistic possibility. This development could have potential for the alleviation of infertility in certain circumstances. It could allow a man unable to produce his own sperm, or a woman unable to produce eggs, to have a child that is genetically their own. It could also, in theory, create profound new possibilities for reproduction such as the conception of a child by combining the genetic material of two women.

2.30 The House of Commons Science and Technology Committee considered the issue of artificial gametes and, whilst recognising their potential to treat infertility, recommended that assisted reproduction using any procedure that does not involve "the union of mature gametes" – sperm and egg – should be prohibited. Therefore, the law should introduce a definition of gamete to include "all haploid human cells", but should distinguish between natural gametes and artificial gametes.[7] However, the Committee also recommended that Parliament should be able to reconsider this matter as technology advances.

2.31 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.

2.32 The Government recognises that it may be necessary to define gamete, egg, and sperm in the HFE Act in order to achieve an effective prohibition on the use of artificial gametes.

Regulation of fresh gametes

2.33 The HFE Act currently regulates the storage and donation of gametes and embryos, and the creation and keeping of embryos outside the body. It does not however regulate the use of a couple's own gametes for treatments which do not involve either storage or the creation of embryos outside the body. This means in practice that certain techniques – such as methods of artificial insemination where sperm is used without being stored – do not come within the scope of regulation, and therefore do not currently require a licence. These techniques include gamete intrafallopian transfer (GIFT) and intrauterine insemination (IUI).[8]

7 *Human Reproductive Technologies and the Law*. See recommendations 20, 99, and paragraph 392. "Haploid human cells" are defined as cells containing a single set of 23 chromosomes, as opposed to the two sets of chromosomes found in "diploid" non-reproductive cells.

8 GIFT is a procedure in which eggs and sperm are mixed and immediately placed in a woman's fallopian tubes. IUI refers to the insemination of sperm directly into the woman's uterus.

2.34 The EU Tissue Directive is directly relevant to this issue as the Directive will bring the use of fresh gametes within the scope of regulation insofar as aspects of safety and quality are concerned. The issue remains, however, of whether and to what extent regulation should apply to fresh gametes beyond matters of safety and quality.

2.35 It may be argued that for the state to intervene in the use of a couple's fresh gametes would be to intrude into what is a relatively straightforward substitute for sexual intercourse between a private couple – in other words that it would be an unjustified invasion of privacy. Moreover, it may be pointed out that the HFE Act was not intended to be a comprehensive statement on all treatments for infertility, but only those matters which gave rise to public concerns. On the other hand, the Government is aware of concerns relating to the use of fresh gametes in conjunction with drugs that stimulate the woman's ovaries to produce more eggs. This can increase the likelihood of multiple pregnancies, which studies have shown create risks to mother and child. This has led to calls for the law to be changed to bring the use of fresh gametes within the scope of regulation.

2.36 In considering the possible need for regulation of fresh gametes, respondents may also wish to look at the matters discussed in section 5 relating to new technologies which enable the selection or 'sorting' of sperm by a variety of means with the intention of producing a child with particular characteristics. For example, the issue of 'sex selection' – being able to choose the sex of a child – is considered there.

2.37 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?

Internet services

2.38 The Government is aware that concerns have been expressed about the operation of internet-based businesses which make arrangements that enable private self-insemination using donated sperm, generally by delivery of the sperm sample to the recipient's home. This activity falls outside the current scope of regulation and does not therefore require a licence, unlike other donor insemination. It is not therefore subject to the oversight mechanisms which follow from licensing.

2.39 The scope of regulation does not cover these businesses because the HFE Act refers to "treatment services", which are defined as "medical, surgical or obstetric services provided to the public or a section of the public for the purpose of assisting women to carry children". As the insemination is essentially private, there is no recognisable "treatment service" to which regulation would apply as the HFE Act currently stands.

2.40 As well as concerns about possible safety risks, the legal parentage of children conceived through the use of donated sperm where this is not undertaken within licensed clinics is not straightforward. This is because the HFE Act makes provisions in relation to parenthood following the use of donor sperm within licensed services. These provisions ensure that donors are not to be regarded as the legal parents of the children conceived. Section 8 considers matters of status and legal parenthood.

2.41 In addition, Parliament has decided that children conceived by donor treatment at licensed clinics will be able to access the identity of their sperm, egg or embryo donor on reaching the age of 18, where the donor registered from 1 April 2005. There would clearly be an anomaly if children conceived via the use of internet-based services were unable to exercise the same rights as other donor-conceived children.

2.42 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?

Regulation of multiple embryo transfer[9]

2.43 Risks to mother and child arising from multiple pregnancies due to the placing of multiple embryos in a woman have been a cause of concern for both the HFEA and the medical professional bodies for some time. We are also aware that good practice in some other European countries, particularly in Scandinavia, has moved further in the direction of single embryo transfer.

2.44 The HFEA's Code of Practice addresses the issue of multiple embryo transfer, and aims to maintain pregnancy rates whilst minimising the risk of multiple pregnancy. The Code states that for women under 40 years of age no more than two embryos should be transferred in a single treatment cycle, and for women aged 40 or over no more than three embryos should be transferred. Where donated eggs or embryos are used, the limit is no more than two embryos regardless of the recipient's age.

9 "Transfer" is the technical term for placing an embryo in a woman.

2.45 Similarly the National Institute for Clinical Excellence has addressed this point, through consideration of the clinical and cost effectiveness of assisted reproduction treatment, again recommending the transfer of no more than two embryos in any one treatment cycle.[10] However, NICE also recommended that further research should be undertaken to improve embryo selection to facilitate single embryo transfers.[11]

2.46 At the same time, the Government recognises that clinical decisions about the number of embryos to be transferred involve a careful balancing of factors including the likelihood of achieving a pregnancy and the potential risks involved in multiple pregnancy, as well as attention to the circumstances of an individual patient.

2.47 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.

Charges for privately-funded treatment

2.48 The House of Commons Science and Technology Committee has made specific recommendations in relation to the remit and functions of the regulator in its recent report on human reproductive technologies and the law.[12] These include powers for the regulator to intervene to ensure that patients are not charged excessive costs by private clinics. Whilst the Government agrees that it is important that patients are appropriately informed about the costs of treatment, we are less convinced of the need for further statutory intervention.

2.49 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.

Regulation of 'standard' *in vitro* fertilisation

2.50 The issues discussed in this section so far are mainly concerned with possible enlargement of the scope of regulation. However, there are also arguments that the scope of regulation should be reduced. The practice of IVF as a treatment for the

10 "Couples should be informed that the chance of multiple pregnancy following in vitro fertilisation treatment depends on the number of embryos transferred per cycle of treatment. To balance the chance of a live birth and the risk of multiple pregnancy and its consequences, no more than two embryos should be transferred during any one cycle of in vitro fertilisation treatment". NICE, Fertility: assessment and treatment for people with fertility problems, February 2004, paragraph 1.10.3.1.

11 Ibid, paragraph 4.5.

12 *Human Reproductive Technologies and the Law*. See especially paragraphs 375, 376, and 394.

alleviation of infertility has been carried on for more than twenty-five years. It has become a well-known and widely practised technique resulting in around two million births worldwide. Implementation of the recent clinical guideline on assessment and treatment for people with fertility problems produced by the National Institute for Clinical Excellence (NICE) will see a greater number of patients receiving infertility treatments funded by the National Health Service.

2.51 Against this background, it may be argued that 'standard' IVF procedures should not be regulated any differently from other health services.

2.52 There are a range of factors which need to be taken into account in relation to this issue. An important consideration is what is actually meant by a 'standard' IVF procedure – for example would this include intra-cytoplasmic sperm injection (ICSI) which involves fertilisation through the injection of a single sperm into an egg. And what about the use of frozen embryos? In practice, it could be very difficult to draw a line between basic techniques and more sophisticated techniques. And this line would need to be constantly redrawn as novel techniques became standard.

2.53 To some extent, the answer to this question will be determined by the rest of this consultation. If it is accepted that there are other reasons to regulate infertility treatments (aside from quality and safety – standards for which will be required as a result of the EU Tissue Directive) then these will presumably apply as much to standard IVF as to newer procedures.

2.54 The Government recognises, however, the need to ensure that regulation is proportionate, and to minimise duplication with any other regulatory requirements. The Government believes that the correct approach is to consider what the requirements of regulation should be, and how they can take account of the fact that IVF procedures have become much more common.

Change to current licensing powers

2.55 The HFEA's current licensing powers enable it to grant licences authorising treatment, storage, or research. The HFEA is able to grant these licences subject to conditions and can therefore tailor a licence to specific circumstances. However the Government is aware of suggestions that the wording of the HFE Act should be modified to make clearer the ability of the regulator to, for example, ensure that certain techniques were only used as part of a clinical trial or to specifically authorise the training of staff.[13]

13 *Human Reproductive Technologies and the Law*. See paragraphs 172 and 173.

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

Application of UK law to persons going abroad

2.57 The HFE Act applies only to activities which take place within the United Kingdom. It does not apply to the provision of treatment or research involving embryos in other countries, although the HFEA does have powers to regulate the import and export of gametes and embryos by licensed UK clinics.

2.58 Although many countries have regulatory systems, some of which are similar to the UK system, there are a variety of different rules, and in some countries there may be no regulation at all. This means that it is possible for UK citizens to seek treatment abroad which may involve procedures that would not be permitted in the UK and vice-versa. This is sometimes referred to as "reproductive tourism".

2.59 The House of Commons Science and Technology Committee considered the issue of people going abroad for treatment, and concluded that attempts to curtail reproductive tourism would not be justified by the seriousness of the offence and, moreover, would be impossible to enforce.[14] There are, however, precedents for laws which apply to activities taking place outside the UK – for example there are criminal penalties in connection with underage "sex tourism" abroad.

2.60 The Government agrees with the Committee that attempts to control "reproductive tourism" would be extremely difficult and probably not justified.

2.61 There may also be concerns about the safety and quality of treatment in some countries. Within the European Union, safety and quality concerns will be addressed by the implementation of the EU Tissue Directive which will introduce common standards of quality and safety. In addition, the HFEA, through its work with the European Society for Human Reproduction and Embryology (ESHRE), is working closely with the European fertility sector in order to advance common standards and regulatory coherence. The Government will ask the HFEA to consider how patients might be better informed about specific safety or legal concerns associated with treatment abroad.

14 *Human Reproductive Technologies and the Law*. See recommendation 94 and paragraphs 382-5.

Section Three – Welfare of the child

3.1 Concerns about the welfare of children – in the broad sense of rights, interests and well-being – underpin many parts of the law and regulation relating to assisted conception treatment. For example, the interests of the children conceived through the use of donated gametes was the key factor in Parliament's recent decision to remove the anonymity of donors (who register from 1 April 2005), so that they can obtain information about their genetic origins on reaching 18 years of age[15].

3.2 As well as informing the legislation in general, taking account of the welfare of the child is an explicit requirement set out in the HFE Act as a condition of all licences to provide assisted conception treatment. Section 13(5) of the Act states that:

> *"a woman shall not be provided with treatment services unless account has been taken of the welfare of the child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who may be affected by the birth".*

3.3 Section 25 of the Act requires the HFEA to give guidance on this requirement in its Code of Practice, and compliance with the Code may be taken into account by the HFEA in its licensing decisions.

3.4 This section of the consultation document focuses primarily on the requirement to take account of the welfare of the child in the Act, and the HFEA's legal duty to give guidance on it. This approach has attracted a range of criticism both in principle and in practice. Some have argued that the welfare of future children to be born as a result of assisted conception treatment is not a matter that should be dealt with in law at all. Others have suggested, following more than a decade of experience, that the practical implementation of considering the welfare of the child in accordance with the HFEA's guidance does not effectively safeguard the child's welfare.

3.5 Earlier this year, the HFEA undertook an extensive public consultation on the guidance it gives to licensed fertility clinics on implementing the welfare of the child provision[16]. The HFEA's consultation considered issues such as the factors which

15 Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004 No. 1511.

16 Tomorrow's Children. A consultation on guidance to licensed fertility clinics on taking into account the welfare of children to be born of assisted conception treatment, HFEA, January 2005.

should be taken into account in making an assessment of the welfare of the child, what enquiries should be made to gather information on which to base an assessment, and how these factors should be weighed in the overall decision to provide (or not to provide) treatment to any patient.

3.6 The issue for the Government's review of the HFE Act is primarily what the *law* should require in relation to the welfare of the child, rather than how the law should be implemented by the HFEA. However, it is useful to look at how the current approach works in order to inform views on this question.

HFEA's guidance on the welfare of the child assessment

3.7 The HFE Act specifically requires the HFEA to include in its Code of Practice guidance for licensed clinics on considering welfare of the child issues. The content of the Code is informed by principles that include:

- people seeking assisted conception treatment have a right to proper consideration of their request, and
- a concern for the welfare of children, which cannot always be adequately protected by concern for the interests of the adults involved.

3.8 The Code currently includes the following:

> *"Those seeking treatment are entitled to a fair assessment. Treatment centres are expected to conduct the assessment with skill and care, and have regard to the wishes and sensitivities of all those involved. This assessment is expected to take into account the following factors relating to patients:*
>
> *(i) the commitment to raise children*
>
> *(ii) the ability to provide a stable and supportive environment for a child/children*
>
> *(iii) immediate and family medical histories*
>
> *(iv) the age, health and ability to provide for the needs of a child/children*
>
> *(v) the risk of harm to children including:*
>
> *(a) inherited disorders or transmissible disease*
>
> *(b) multiple births*
>
> *(c) problems arising during pregnancy*
>
> *(d) neglect or abuse*
>
> *(e) the effect of a new baby or babies upon any existing child of the family."*

3.9 The Code of Practice goes on to specify additional factors to be considered, particularly in circumstances where donated gametes are used, or where a surrogacy arrangement is involved. The Code sets out enquiries which clinics are expected to make and the need to take account of all available information in any decision to refuse to provide treatment. If the provision of treatment is refused, treatment centres are expected to explain the reasons for the refusal, and any remaining options for the patient.

Criticisms of the current approach

3.10 The current requirement to take account of the welfare of the child has generated a great deal of debate about the proper role of the state in relation to reproductive decisions. Some have argued that as the law does not intervene in the reproductive choices of people who are able to conceive naturally, it is therefore discriminatory to intervene where people happen to have fertility problems. Furthermore, as the requirement to consider the welfare of the child applies only to licensed clinics, it does not apply to all assisted conception treatment or surgical procedures aimed at restoring fertility, and therefore the law is inconsistent.

3.11 Other criticisms of the current approach include:

- it is unnecessary, because it adds little to good medical practice
- it does not set a clear barrier to treatment, because it only requires that welfare is "taken into account"
- the HFEA's guidance is too prescriptive or bureaucratic in defining the factors that should be taken into account, and enquiries that should be made.

3.12 The House of Commons Science and Technology Committee considered the welfare of the child provisions of the HFE Act in its recent report *Human Reproductive Technologies and the Law*. The Committee made several criticisms about the requirement to take account of the welfare of the child, including the current wording of section 13(5) and how it has been implemented in practice.[17]

17 See paragraphs 91 to 107, and recommendations 21 to 24.

3.13 The Committee recommended that section 13(5) should be abolished in its current form, on the basis that it discriminates against people with fertility problems, is impossible to implement, and is of questionable practical value. Instead, the Committee recommended that:

> *"the minimum threshold principle should apply but should specify that this threshold should be the risk of unpreventable and significant harm. Doctors should minimise the risks to any child conceived from treatment within the constraints of available knowledge but this should be encouraged through the promotion of good medical practice not legislation".*[18]

3.14 However, there are also views that the Act's current requirement to take account of the welfare of the child does not go far enough. It does not, for example, make the child's welfare the overriding consideration in deciding whether treatment should be provided, but leaves this as a matter to be considered alongside others. Some have argued that the provision of assisted conception treatment should be more similar to adoption, which requires extensive assessment of the intending parents and makes consideration of the child's best interests the "paramount" consideration in law.

Is welfare of the child a matter for the HFE Act?

3.15 Assisted conception treatment is unlike any other branch of medicine in that providing a 'cure' for the patient may result in the creation of another person with needs, rights and interests. Children are not conceived by accident within treatment services, but by a deliberate process over a period of time. The use of the clinician's skill to bring about the creation of the child places a responsibility on the clinician which goes beyond the usual responsibility for the welfare of the patient.

3.16 In addition, it may be argued that there are specific risks associated with assisted reproduction beyond those which may be faced by couples able to conceive naturally. For example, assisted conception could enable a woman to become pregnant after the age at which she could conceive naturally. This could give rise to concerns not only about the woman's ability to carry the child successfully but also her ongoing ability to care for the child.

18 *Human Reproductive Technologies and the Law*. See recommendation 24, paragraph 107. The "minimum threshold" principle is referred to in paragraph 96 of the Committee's report, and is distinguished from the alternative "maximum" and "reasonable" threshold approaches. The minimum threshold principle places the greatest emphasis on the autonomy of the intending parents. A fuller discussion of these principles can be found in the HFEA consultation paper, Tomorrow's Children, referred to in footnote 16.

3.17 Those who argue for society having the power in principle to intervene in the reproductive choices of people requiring assisted conception, but not in the reproductive choices of people able to conceive naturally, may do so on the basis that this represents a justifiable difference in treatment rather than discrimination. In other words, that there is a difference between preventing someone from exercising their capacity to reproduce, and enabling someone to reproduce who could not otherwise do so.

3.18 Whether the force of law is thought to be necessary is perhaps a matter of judgement based on two main issues:

- whether the risks of harm involved could have such an adverse impact on the welfare of the child that their consideration could not be left to, for example, good medical practice or guidance alone
- whether it is possible in practice to make reasonable judgements about the likely risks of harm – for example, it has been argued that it is very difficult, if not impossible, for medical staff to make judgements about issues such as the future commitment of parents to raising children, or their future ability to provide a supportive environment.

3.19 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.

Expressing the welfare of the child requirement in the HFE Act

3.20 If the principle of having a welfare of the child requirement in the HFE Act is maintained, the question arises as to how that requirement should be expressed.

3.21 The Act could, for example, have a simple reference to considering the welfare of the child but leave the detail of that consideration for clinicians rather than requiring the HFEA to provide guidance. The professional duty of clinicians to act according to good medical practice principles such as "first, do no harm" and the natural concern of the patients for the welfare of their offspring may be thought to provide sufficient safeguards of the welfare of the child. The professional duty of the clinician to follow good medical practice could be reinforced by guidance from the professional bodies, such as the Royal College of Obstetricians and Gynaecologists.

3.22 The state does, of course, intervene to protect vulnerable children through social services, which can include the removal of children into care, and it may be argued that these arrangements by themselves give sufficient attention to the welfare of

children as and when certain types of problems arise. This view would suggest that clinicians should only take into account matters such as the likelihood of medical problems, and should not be expected or required to take account of the environment in which the child is likely to be brought up. The House of Commons Science and Technology Committee considered this approach and recommended that if there is reason to believe that children born as a result of assisted reproduction are at increased risk then healthcare professionals can alert social services at an early stage.

3.23 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.

3.24 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?

3.25 Alternatively, the law could be reformulated to concentrate more clearly on the prevention of harm, rather than simply referring to "welfare". This could go together with a more targeted approach. It is argued that undertaking an assessment of each and every patient is unnecessary and wasteful, and it would be better to focus on those cases where there is a clear risk of harm to the child. This would involve making a presumption in the majority of cases that there were no concerns about the welfare of the child, unless the clinician had reason to believe otherwise.

3.26 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?

The need of the child for a father

3.27 The current wording of section 13(5) of the HFE Act refers specifically to "the need of the child for a father" as a factor to be taken into account when assessing the welfare of the child. Some argue that it is inappropriate to single out a particular factor and not others – for example, there is no mention of the need of the child for a mother. This provision has also been described as discriminatory and out of date insofar as it does not reflect the range of family structures that now exist in this country. This is because it is suggested that it could be an obstacle to single women and lesbian couples being able to access treatment services. It is also suggested that concerns about possible adverse effects on the gender development and emotional wellbeing of children born in these circumstances are unfounded.

3.28 Academic research undertaken to date tends to support this view. However, early research in this area, and most longitudinal studies, are based on children of mothers separated from previous heterosexual relationships. There are few studies of children raised from infancy in lesbian parent families. These studies cannot therefore be considered as providing conclusive evidence either way about the value of the father's role in children's development, although they do point to the quality of parenting, rather than the parents' gender, as being the factor of prime importance. Other 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.[19]

3.29 The current guidance in the HFEA's Code of Practice states: "[w]here the child will have no legal father the treatment centre is expected to assess the prospective mother's ability to meet the child's/ children's needs and the ability of other persons within the family or social circle willing to share responsibility for those needs".

3.30 Some would prefer to see the reference to the "need for a father" dropped from the Act altogether, or subsumed into the more general duty to consider the welfare of the child. The Science and Technology Committee considered that:

> *"the requirement to consider whether a child born as a result of assisted reproduction needs a father is too open to interpretation and unjustifiably offensive to many. It is wrong for legislation to imply that unjustified discrimination against "unconventional families" is acceptable."* [20]

3.31 As a general rule the Government believes that it is better for a child to have both a father and a mother. The Warnock report, on which the HFE Act was based, expressed the same view although it recognised that it was impossible to predict with any certainty how lasting such a relationship would be, and did not make explicit recommendations on this point.

3.32 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"?

19 A longitudinal study of children from infancy to age 12 is reported in Fiona MacCallum and Susan Golombok "Children raised in fatherless families from infancy: a follow-up of children of lesbian and single heterosexual mothers at early adolescence." Journal of Child Psychology and Psychiatry 45:8 (2004). This article also recounts the history of research in this area, including studies showing adverse effects of single parenthood.

20 *Human Reproductive Technologies and the Law*. Paragraph 101.

Section Four – The use and storage of gametes and embryos

4.1 The HFEA is able to grant licences authorising certain types of assisted conception treatment, embryo research, and the storage of gametes and embryos. The HFE Act sets out the mandatory conditions that apply to all licences, and several specific conditions that apply to each type of licence. These range from requirements to obtain written consent for the use or storage of an embryo, to the requirement to offer a suitable opportunity for counselling on the implications of treatment or donation.

4.2 In effect, these licence conditions are legal constraints on licensed centres who are obliged to act in accordance with them, often with additional guidance provided by the regulator in the form of the HFEA's Code of Practice.

4.3 There are therefore two broad issues for the Government's review of the HFE Act:

- whether these regulatory requirements continue to be justified, taking into account the five principles of good regulation – proportionality, accountability, consistency, transparency and targeting, and
- whether the wording of the law as it currently stands remains appropriate.

4.4 A number of legal challenges concerning the storage and use of embryos have been mounted over recent years. These have involved issues such as the joint consent required for the storage and use of an embryo from the persons whose gametes were used in its creation, and what should happen if those persons' consents become incompatible because of disagreement.

4.5 This section considers a range of issues relating to the storage and use of gametes and embryos, including the requirements around consent and counselling, statutory limits on storage periods for gametes and embryos, the provision of information to patients and who should be responsible for setting policy on payments to gamete donors.

Requirements for written consent

4.6 The HFE Act sets out extensive requirements for individual consent to a range of activities. These are in addition to any general requirements for consent as a matter of common law. Schedule 3 of the HFE Act contains the detail of the consent requirements, and the HFEA's Code of Practice gives additional guidance and also provides appropriate standard forms for licensed centres to record consent.

4.7 The consent provisions are centred around the idea of "effective consent", which *must be in writing* and not have been withdrawn. The requirement for effective consent applies to the following activities:

- *use of gametes for the treatment of others* (i.e. donation of eggs and sperm)
- *in vitro fertilisation and subsequent use of an embryo* – the consent must specify one or more of (a) providing treatment services to the person giving consent and another specified person, (b) donation for the treatment of others, (c) use for the purposes of any project of research
- *storage of gametes and embryos* – the consent must specify the maximum period of storage (subject to a statutory maximum), state what is to be done with the gametes or embryos if the person who gave the consent dies or is unable because of incapacity to vary the terms of the consent or to revoke it, and may also specify conditions subject to which the gametes or embryos may remain in storage.

4.8 Requirements for consent were recommended in the Warnock report as part of a process of ensuring that reproductive decisions involving certain medical interventions should be fully informed and understood. Written consent provides a measure of evidence that a process of consideration and reflection, taking account of the relevant facts, has happened. It also helps to ensure that a person's gametes or embryos cannot be used in ways that they did not intend by providing an enduring statement of their wishes.

4.9 However, it could be argued that specifically requiring *written* consent imposes an unnecessary burden on licensed services. The requirement for written consent does not apply to the use of gametes where storage is not involved and the gametes are used for the treatment of the couple themselves through techniques such as IUI and GIFT (not currently within the scope of regulation, but due to be brought within the HFEA's remit by implementation of the EU Tissue Directive). This may be thought to be inconsistent with the requirement for written consent for the creation of an embryo for IVF treatment.

4.10 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?

4.11 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?

Consent to storage

4.12 The consent provisions of the HFE Act, and their interaction with common law requirements for consent were considered in depth in a Department of Health-funded review that reported in July 1998. This review was led by Professor Sheila McLean of the School of Law, University of Glasgow, and included a public consultation exercise in 1997.[21]

4.13 The McLean review considered in particular the issues associated with people who are unable to provide the necessary consent due to incapacity. For example, under the HFE Act as it stands, even where the removal of a person's gametes could be judged by a court to be in the best interests of that person, the storage of those gametes would fall foul of the requirement for written consent to storage. This type of case could occur either with adults who are incapacitated through injury or illness, or with children who have not yet developed the capacity to deal with those issues. The idea behind removing and storing their gametes would be to preserve their capacity to reproduce in future.

4.14 The Government accepted, in response to Professor McLean's report, that the law should be changed to address these points when Parliamentary time allowed. Questions relating to the removal and use of gametes were subsequently included in a consultation on changes to the law on human organs and tissues, published in July 2002.[22]

21 Respectively "Review of the common law provisions relating to the removal of gametes and of the consent provisions in the Human Fertilisation and Embryology Act 1990", published July 1998, and "Consent and the law. Review of the current provisions in the Human Fertilisation and Embryology Act 1990 to UK Health Ministers", published September 1997.

22 "Human Bodies, Human Choices", The Law on Human Organs and Tissues in England and Wales, Department of Health, published July 2002.

4.15 In response to the consultation, most people felt that:

- it should be possible to store the gametes of a child for their future use, if consent was given by the parents, and that the courts should have a power to consent to the continued storage of gametes once someone reaches the age of 18, if they lack the capacity to consent themselves at that point
- removal of gametes from an adult who lacks capacity should be in accordance with the principles governing other medical interventions on that person.

4.16 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?

4.17 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?

Withdrawal or variation of consent

4.18 Where consent is given in accordance with the HFE Act requirements, it may be withdrawn, or any terms of the consent may be varied, by the person who gave consent. The ability to vary or revoke consent ceases once the embryo has been used in providing treatment services or in a project of research. With regard to an embryo, the consent of both of the persons whose gametes were used in its creation is required for the continued storage and use of that embryo. Therefore if the consent of one of those persons is withdrawn, the embryo can no longer continue to be stored lawfully and must be allowed to perish. Similarly, the embryo cannot be used for treatment or research without the effective consent of both persons.

4.19 The Government is not persuaded by arguments that would clearly prioritise the rights of one partner over the other. For example, it could be argued that it would be more in line with natural conception if the woman alone were able to decide on the use of the embryo once it has been created. The Government does not propose to change the legal position that the consent of both parties whose gametes were used in the creation of an embryo should continue to be required for its use in treatment or research.

4.20 However, the Government is aware of views that the withdrawal of the consent of one of the parties to the storage of an embryo should not automatically result in the embryo being allowed to perish. An alternative approach would be to require the withdrawal of both parties' consent in order to allow the embryo to perish, and

otherwise for it to continue in storage until the statutory maximum storage period. It is argued that this would allow a 'cooling-off' period, and therefore the potential for agreement to be reached on any subsequent use of the stored embryo.

4.21 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.

Statutory storage periods for gametes and embryos

4.22 The Warnock Committee considered issues around the prolonged storage of human gametes and embryos, including legal issues which could arise such as problems with inheritance. The Warnock report recommended automatic five-yearly reviews of stored gametes and a maximum ten-year period of storage for embryos. The ten-year limit took account of concerns about the possible effects of long-term storage as well as legal and ethical complications that might arise due to disputes between the couple who had stored the embryo.

4.23 The HFE Act sets out maximum permissible periods for the storage of gametes and embryos. These can be found in section 14 of the Act as part of the conditions on storage licences. The initial storage periods set in the legislation are ten years in respect of gametes and five years in respect of embryos. However, section 14 also allows regulations to be passed by Parliament to extend or reduce these periods, and regulations were made in 1991 and in 1996 which extended these storage periods in certain circumstances for gametes and embryos respectively.[23]

4.24 However, the law does not currently permit storage beyond the original statutory limit for the purpose of donation to someone who was not the intended recipient when the gametes or embryos were first placed in storage. In practice this could have the effect of preventing a woman who has had a child using the gametes of a particular donor from having subsequent children using the same donor where the statutory storage period has expired. Another scenario is where embryos have been stored, but the woman becomes unable to carry a child and therefore wishes to use a surrogate.

4.25 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?

23 The Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991, Statutory Instrument 1991, No. 1540, and The Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996, Statutory Instrument 1996, No, 375.

4.26 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?

Requirements to offer counselling and provide relevant information

4.27 The HFE Act specifies that before giving consent a person must have a suitable opportunity to receive proper counselling about the implications of taking the proposed steps *and* must be provided with such relevant information as is proper.

4.28 The Warnock Committee believed that counselling should be available for infertile couples and for donors, in particular to ensure that they understood the implications of what they were embarking on, what rights and duties they had, and where difficulties could be expected to arise. The type of counselling envisaged in the Warnock report was aimed at helping individuals to understand their own situation and make their own decisions.

4.29 The provision of appropriate information was similarly intended to ensure that any consent given is fully informed. Guidance on both counselling and the provision of appropriate information is provided through the HFEA's Code of Practice. The giving of information is expected to be distinct from the requirement to offer counselling, not least because there is no obligation to accept an offer of counselling. The type of information to be provided is expected to cover a range of issues including medical and legal matters, as well as the centre's policy on selecting patients and information about costs.

4.30 In addition to the licensed centre's obligation to provide relevant information, the HFEA itself has general functions under the Act to:

- publicise the services provided to the public by the Authority and services provided by clinics
- provide, to such extent as it considers appropriate, advice and information for persons to whom licences apply or who are receiving treatment services or providing gametes or embryos for use for the purposes of activities governed by the Act, or who may wish to do so.

4.31 The HFEA fulfils this responsibility in a number of ways, including publication of a guide to infertility incorporating a directory of clinics[24]. This publication aims to provide people seeking treatment with information and guidance to enable them to make the best decisions in their own particular circumstances.

24 The HFEA guide to infertility and directory of clinics 2005/6, HFEA.

4.32 The House of Commons Science and Technology Committee, in its recent report on human reproductive technologies, considered the issue of information about value for money in assisted conception treatments after hearing concerns that some of the services being offered to patients were not justified by evidence of their value.[25]

4.33 The Committee recommended that clinics, whether private or NHS, must make it clear when they are offering services and treatment that lie outside of the National Institute for Clinical Excellence's clinical guideline on infertility treatment.[26]

4.34 The Government accepts that assisted conception treatment, and gamete and embryo donation are complex and fast-moving areas, and that people receiving treatment or providing gametes or embryos should have access to appropriate information in making their decisions. However, in considering the current legal requirement on licensed services to provide information, the Government must also have regard to the principles of good regulation and consider whether the provision of information could be a matter more appropriately dealt with as good professional practice.

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

4.36 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?

4.37 The House of Commons Science and Technology Committee considered the issue of counselling, including whether it should be mandatory to *receive* counselling. The Committee thought that on balance the current wording of the law was appropriate insofar as it only required that a suitable *opportunity to receive* counselling was offered but not necessarily taken up. Rather the Committee believed that there was an issue about a lack of appreciation of the value of counselling by clinicians, and recommended that counsellors should work harder to develop an evidence base to support their practice.[27]

25 *Human Reproductive Technologies and the Law*. See paragraph 292. See also paragraphs 2.48 and 2.49 of this document about charges for privately-funded treatment.

26 Fertility: assessment and treatment for people with fertility problems. National Institute for Clinical Excellence, Clinical Guideline 11. Published February 2004.

27 *Human Reproductive Technologies and the Law*. See paragraphs 163 to 168.

4.38 The Government is aware of evidence of the benefits of counselling in other settings and believes that counselling can play a valuable role in helping patients make informed reproductive decisions and understand the implications of those decisions. However, we are not convinced that a requirement to offer counselling should necessarily be set out on the face of the legislation, since the same is not true of any other area of medical treatment.

4.39 It could also be argued that there is a case for dealing differently with treatments involving donated gametes – and only requiring counselling to be offered in these circumstances.

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

4.41 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?

Remuneration of donors

4.42 The HFE Act specifies, as a general condition of all licences granted under the Act, that no money or other benefit shall be given or received in respect of any supply of gametes or embryos unless authorised by directions from the HFEA. The HFEA has made directions in relation to payments for donors from time to time, and the HFEA's Code of Practice includes extensive guidance on egg-sharing arrangements (where a woman agrees to donate some of her eggs retrieved during a treatment cycle) which may involve payments in kind. At present the HFEA's policy is that gamete donors may be paid no more than £15 plus reasonable expenses. (The HFEA is currently reviewing this policy so it may change shortly).

4.43 The House of Commons Science and Technology Committee considered the issue of payments to donors and concluded that as decisions about remuneration of donors could provide an incentive or a disincentive to donate, this was a decision best left to Parliament.[28]

4.44 In this context it is important to note that the EU Tissue Directive will set common quality and safety standards for EU Member States in relation to human tissues and cells intended for human applications. Article 12 of the Directive says that Member

28 *Human Reproductive Technologies and the Law*. See paragraphs 161-2.

States shall endeavour to ensure that donations are voluntary and unpaid, but donors may receive compensation, limited to making good the expenses and inconveniences related to the donation.

4.45 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.

4.46 In addition, as the current controls on payments relate to licensed services, there are circumstances outside of the scope of regulation where payments could be made in respect of the supply of gametes. This could, for example, include the purchase of eggs for research (provided that the research is not licensable). There are concerns that people either in the UK or overseas could be exploited by the prospect of rewards for supplying their gametes in these circumstances. On the other hand, as unlicensed research would not involve the creation of an embryo, it could be argued that this should be a legitimate matter for individual choice.

4.47 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.

Section Five – Reproductive choices: screening and selection

5.1 There have been a number of significant developments in the ability of clinicians to screen and select gametes and embryos since the HFE Act was passed in 1990. Whereas IVF treatment generally involves selection of the patients' most viable embryos, new techniques have increased the scope for potential parents to make choices about the characteristics of their offspring such as whether they carry an inherited disease.

5.2 Technological developments in this area have met with a range of responses from the public. Over the past decade, new terms such as 'designer babies' and 'saviour siblings' have been invented. Commonly held views range from indignation at attempts to 'play God' or 'interfere with nature', to joy and relief at the prospect of avoiding hereditary disorders and diseases. Themes brought into play include reproductive freedom, the welfare of the child, and a contrast between treating children as 'gifts' and as 'commodities'.

5.3 The current law contains a number of relevant restrictions, such as a prohibition on altering the genetic structure of an embryo. Some techniques, such as screening of embryos before they are placed in the womb, have been developed within licensed services and are subject to regulation. By contrast, new techniques of selecting the sex of a child by "sperm sorting" (where the sperm is not from a donor or frozen) currently are not covered by the law.

5.4 This section considers the extent to which the ability to choose the characteristics of children through assisted reproduction should be subject to law and regulation.

Techniques for screening and selection

5.5 Currently developed techniques include:

- preimplantation genetic diagnosis (PGD). This is a technique involving the creation of several embryos and selection of those to be placed in a woman based on the results of biopsy using one or more cells from the embryo
- preimplantation genetic screening (PGS). This refers to techniques used to select embryos free from chromosomal abnormalities

- "sperm sorting" – dividing a semen sample into sperm carrying male or female chromosomes, to be used for artificial insemination or the creation of an embryo in vitro.

The current legal position

5.6 Paragraph 1(1)(d) of schedule 2 to the HFE Act provides that a licence may authorise, in the course of providing treatment services, "practices designed to secure that embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose". This is restricted by a number of prohibitions including:

- licences for treatment cannot authorise altering the genetic structure of any cell while it forms part of an embryo (schedule 2(1)(4))
- licences cannot authorise replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo (section 3(3)(c))
- in addition, the Human Reproductive Cloning Act 2001 makes it an offence to place in a woman a human embryo that has been created by a method other than fertilisation.

5.7 The HFEA's decision to license PGD under the HFE Act has been challenged in the courts. This resulted in the House of Lords confirming that the HFE Act *does* give the HFEA the power to license the use of PGD (and PGS), including in combination with tissue-typing for the benefit of a seriously ill sibling.[29]

5.8 The HFEA has further powers to impose licence conditions and to make directions which are binding on licence holders. Additional guidance is provided in the HFEA's Code of Practice.

5.9 Purposes for which the screening or selecting of embryos or gametes are allowed by the HFEA are:

- so that the child bears similar physical characteristics to the infertile partner or couple where donor gametes are used
- to avoid inherited genetic disorders and diseases
- to avoid sex-linked diseases (such as Duchenne muscular distrophy)
- to screen out chromosomal abnormalities to reduce the risk of miscarriage

29 In R (Quintavalle) v Human Fertilisation and Embryology Authority. Judgement published 29 April 2005.

- so that the child is able to be a tissue donor for a seriously ill sibling (this involves a process known as 'tissue-typing').

5.10 Sperm sorting, however, currently falls outside of the scope of regulation where it is undertaken using the "fresh" sperm of a man for the insemination of his wife or partner, where the sperm has not been stored and is not used in IVF.

Concerns about screening and selection

5.11 It could be argued that parents have always sought to influence their children's characteristics, just as they have always tried to influence matters such as their educational development. In particular, attempts to control the child's sex have a long history, with people turning to 'old wives tales' about diet or the timing of sexual intercourse. Advances in reproductive technologies have, however, dramatically increased both the ability to intervene in the reproductive process and to make choices with a high probability of achieving the desired outcome.

5.12 The basic parameters of the current law reflect what seems to be a widely held view that there is a need for regulation of the uses of reproductive technology in this area. However, some would prefer to see Parliament taking decisions in novel cases, or decisions being left to patients in consultation with their doctors. There are also a variety of views ranging from arguments that as a matter of principle the choosing of characteristics by whatever means should not be allowed, to arguments that if the technology is available, then people should be free to use it to full effect.

5.13 Commonly expressed concerns include:

- the creation and destruction of those embryos which are not selected. Clearly there will be a range of opinions on this point depending on how the status of the human embryo is viewed
- fear of heading down a "slippery slope" towards choosing characteristics for sinister motives, or selection on the basis of "trivial" characteristics such as eye or hair colour
- that screening and selection has the potential for children to be treated as "products", or simply the means of a parent's self-expression rather than as human beings in their own right
- that screening-out embryos with genetic impairments implies that children with inherited disabilities are of less worth than others and could lead to negative attitudes towards people with those disabilities

- the possibility that techniques used to *screen-out* disabilities or impairments could also be used for *screening-in*. There has been a well-publicised case in the United States, of a deaf couple who wished to select a deaf donor so that the resulting child would also be deaf, and therefore share more closely the parents' experience of the world. The House of Commons Science and Technology Committee considered this issue and concluded that the desire to select a child who would suffer obvious discomfort or worse was an area needing further debate.[30]

Future regulation of selection and screening

5.14 It is difficult to predict new developments that may arise in the future in this area, whether in this country or overseas. However, the current trend is toward greater use of preimplantation genetic diagnosis (PGD) for a wider range of diseases and disorders, and the development of new techniques for selecting gametes.

Embryo screening and selection

5.15 Under the HFE Act the HFEA has a relatively wide discretion to license the use of techniques such as PGD. Following public consultation in 1999 the HFEA's policy has been to license the use of PGD to screen for serious diseases only. These have generally been diseases which have early onset and for which effective treatments are not available. It may be argued, however, that it should be a matter for legislation to set out more specifically the circumstances in which techniques such as PGD can be used. For example, a distinction could be drawn in law between medical and non-medical interventions, or the law might be framed to allow embryo screening and selection to avoid serious disorders only.

5.16 The House of Commons Science and Technology Committee considered the current regulation of embryo screening and selection. It concluded that potential uses of PGD are limited because it can only be used to screen out disorders rather than be used to create "designer babies". The Committee saw no reason for a statutory regulator to decide which particular disorders can be screened out using PGD, and recommended instead that decisions should be made by patients and their doctors within clear boundaries set by Parliament.[31]

30 *Human Reproductive Technologies and the Law.* See paragraphs 144-5.

31 *Human Reproductive Technologies and the Law.* See recommendations 27 and 28.

Preimplantation tissue-typing

5.17 PGD in conjunction with tissue-typing has been undertaken in a very small number of cases. The intention has been to select an embryo whose cells will provide a tissue match for an existing sibling. In this way cells from the umbilical cord blood can be used in the treatment of a seriously ill brother or sister. The HFEA's current policy, having reviewed the safety of the technique and the medical, psychological and emotional implications, is to license PGD with tissue-typing essentially as a last resort. It is the HFEA's policy to consider these individual cases on their own merits.

5.18 The House of Commons Science and Technology Committee also considered the matter of PGD in conjunction with tissue-typing and concluded that there were no compelling reasons for a regulator to make judgments on whether a family could seek preimplantation tissue-typing, provided the circumstances are within parameters set by Parliament.

5.19 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?

5.20 Do you think that there should be a prohibition on deliberately screening *in*, or selecting *for* impairments or disabilities – as opposed to screening *out*, or selecting embryos free from impairments or disabilities?

5.21 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?

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

5.23 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?

Screening and selection of gametes

5.24 The use of donated gametes in treatment services is subject to regulation under the HFE Act. The HFEA's Code of Practice provides guidance to treatment centres about the selection of donated gametes. This includes, for example, the expectation that those seeking treatment are not to be treated with gametes provided by a donor of different physical characteristics to the infertile partner, unless there are compelling reasons for doing so.[32]

5.25 Similarly the use of a couple's own gametes in treatment services involving IVF, or where the gametes are stored, are also subject to regulation. However, where the couples own gametes are used "fresh" (that is not involving storage or IVF), regulation under the HFE Act does not apply. Therefore the use of newly developed techniques such as sperm sorting are not subject to regulation in those circumstances.

5.26 In theory, selection of gametes prior to conception could provide an alternative to selection of embryos following conception. It may be argued that selection of gametes would be less open to ethical objections because embryos would not need to be created unnecessarily. However, other objections and concerns – such as the risk of encouraging negative attitudes toward persons with disabilities – could remain.

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

Sex selection

5.28 The HFE Act does not prohibit sex selection of embryos. Sex selection using PGD is subject to regulation by the HFEA. Currently the HFEA only allows sex selection to avoid sex-linked disorders such as haemophilia.

5.29 Sex selection using new "sperm sorting" procedures is not covered by the HFE Act. The question of whether "sperm sorting" should be brought within the HFE Act is dealt with in paragraphs 2.33 to 2.37.

5.30 In 2002/03 the HFEA undertook an extensive public consultation on the issue of sex selection. This included written consultation, discussion groups, and a MORI survey of 2,000 people representative of the UK population. This found strong public opposition to sex selection for non-medical reasons.

32 HFEA, Code of Practice, 6th Edition, paragraphs 3.18 and 3.19.

5.31 The House of Commons Science and Technology Committee, however, considered the issue of sex selection and found no adequate justification for prohibiting the use of sex selection for family balancing – that is, where a family already have children of one gender and wish to 'balance' their family with a child of the other gender.[33] This was on the basis that family balancing would be unlikely to result in harm to society through an overall gender imbalance. Some countries such as Belgium and Jordan allow sex selection for non-medical reasons. Others such as Israel allow non-medical sex selection only for family balancing purposes.

5.32 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?

Genetic modification of gametes and embryos in treatment

5.33 The interventions already described involve sorting or selecting from a given set of characteristics. However, it may become possible in future to correct defects or repair damage by modifying gametes or embryos directly. If this could be done safely, it is argued that fewer embryos would need to be created and therefore fewer subsequently be allowed to perish.

5.34 The possibility of being able to 'repair' gametes or embryos raises the concern that it could be difficult to distinguish between what would constitute 'repair' and what might be thought of as 'enhancement'. In theory, 'enhancement' could mean adding a characteristic that was not originally present, or attempting to improve attributes such as intelligence or athletic ability. Arguably, it is this issue that is at the heart of concerns about so-called "designer babies".

5.35 Modification of gametes and embryos, whether for repair or enhancement also raises the potential risks of "germ line" changes. This means changes which not only affect an individual, but result in changes which are passed down through the generations by also affecting reproductive cells.

5.36 It has generally been held that the potential risks of germ line interventions, given the current state of scientific knowledge about the possible effect on future generations, demand that such interventions should not be attempted. This is reflected in a range of international agreements and also features in UK law. For example, section 19(3) of

33 *Human Reproductive Technologies and the Law.* See paragraphs 131-142.

the Clinical Trials Regulations 2004 outlaw clinical trials involving products for gene therapy if the use of those products in that trial would cause modifications to any participant's germ line genetic identity.

5.37 The House of Commons Science and Technology Committee recently considered genetic modification of embryos as part of its inquiry into human reproductive technologies and the law.[34] The Committee drew attention to the potential benefits of germ line therapy in terms of treatment of serious diseases, if such therapies could be undertaken safely and effectively. The Committee therefore recommended:

- that there should not be an absolute prohibition on genetic modification of embryos in research (discussed in section 9 of this document)
- the existing prohibition on genetic modification of embryos in treatment should be capable of being relaxed through regulations passed by Parliament, in tightly controlled circumstances if and when the technology is further advanced.

5.38 The Government recognises the very serious safety concerns associated with genetic modification of gametes and embryos to be used in treatment. **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.**

34 *Human Reproductive Technologies and the Law.* See paragraphs 78-82.

Section Six – Information and the HFEA register

6.1 The HFE Act requires licensed centres to collect, record and maintain information and to forward information to a central register maintained by the HFEA. This information is subject to strict confidentiality provisions set out in the Act about the circumstances in which it may be released and the uses to which it may be put.

6.2 There are a number of reasons why the mandatory collection of information from centres may be thought to be necessary or desirable. For example, it could provide data on outcomes from different procedures which may help patients make choices about their treatment. Collected data could also provide a basis for follow-up research on the long-term safety of treatments.

6.3. The question is whether the current legal requirements with regard to information remain justified and appropriate. In addressing this issue, the Government has regard to the principles of good regulation – proportionality, accountability, consistency, transparency and targeting – which are aimed at ensuring that regulatory requirements are necessary, fair, effective, affordable and enjoy a broad degree of public confidence.

The Warnock Report

6.4 The Warnock Committee considered a number of issues broadly relating to data and information arising from treatment services.[35] The Committee's recommendations ranged from the collection of statistics on infertility services to the right of donor-conceived people to access information about their donor.

6.5 In particular, the Committee proposed a nationally-maintained database of gamete donors, together with limits on the number of births as a result of any one individual's donations, as a means to minimise the possibility of unwitting incest or the risks of transmission of inherited disease. The Committee's report noted that a central register of births could also enable donor-conceived children to discover information about their donor.

6.6 Public consultation following the Warnock report found in particular that there were strongly held views favouring a central record of births as a result of donation. This was thought to be essential to ensure the child's right of access, as an adult, to an

35 The Warnock report. See especially paragraphs 4.21, 4.26 and 13.9.

accurate record of the biological facts of his birth and to information about the donor, and also as a means to ensure that where the donor-conceived person intended to marry, there was no possibility of a prohibited relationship with the intended spouse through their being closely related.

What the HFE Act requires

6.7 The HFE Act makes the keeping of records a condition of all licences, and enables the HFEA to specify, for instance, the format in which records must be kept and for how long.[36] The Act effectively makes the recording of certain information about the provision of treatment services mandatory on the part of the licence holder, and requires information to be given to the HFEA. This includes information about those receiving treatment and the treatment provided for them, the use of donated gametes, and the birth of any child as a result of the provision of treatment services.

6.8 The HFEA's Code of Practice places further requirements on centres to record information, including for example a written record of the information that has been considered in respect of the welfare of the child, which is expected to reflect the views of those who were consulted in reaching a decision, and the views of those seeking treatment.

6.9 The Act requires the HFEA to maintain a confidential register of information about donors, patients and treatments provided by licensed centres. The register was set up on 1 August 1991 and contains information about children conceived through licensed treatments from then on. Under the Act, donor-conceived people can find out whether they are related to a person they intend to marry and, if aged 18 or over, can have access to information held on the register about their donor. The Act makes clear that a person requesting access to the information from the register must have been given a suitable opportunity to receive proper counselling about the implications of receiving such information.

6.10 Where donors of gametes or embryos were registered from 1 April 2005, the donor-conceived person will, on reaching 18, have the right of access to information that includes the name of the donor.

6.11 Sections 33 to 35 of the HFE Act set out the legal restrictions on disclosure of information and specific exemptions to those requirements in relation to certain judicial proceedings. Restrictions on disclosure relate both to information held

36 See in particular sections 13 and 24 of the HFE Act.

centrally and to information held by the licensed centre. These restrictions are intended to safeguard the confidentiality of information relating to patients, donors and children.

Information relating to donors and donation

A central register

6.12 Maintenance of a register, recording information about gamete and embryo donors and donation used in treatment in the UK is one of the core functions of the HFEA. Whilst there are possible alternative approaches that could fulfil the same function, including reliance on locally held records, the Government believes that a single register at national level, providing a central point of access and transparent access criteria remains the most appropriate option.

6.13 The House of Commons Science and Technology Committee, in its recent report on human reproductive technologies made a number of recommendations regarding information about gamete and embryo donation.[37] The Committee concluded that a centrally maintained database in respect of donor treatment should remain a core function of the regulatory body.

6.14 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?

Information about donors

6.15 The House of Commons Science and Technology Committee has recommended that donor-conceived children should be able to access non-identifying information about their donor as soon as they are told by their parents about the facts of their conception rather than waiting until they are 18. The Committee reached this conclusion on the basis that parents might be unwilling to tell their child that he or she was donor conceived if no information about the donor is available to the child.

6.16 The Government rejects this argument. Parents receive non-identifying information about the donor at the stage of treatment, and may contact the clinic (or if necessary the HFEA) at any later stage for non-identifying information that they can then pass on to the child. The Government does not think it is appropriate for the child to approach the clinic direct for such information.

37 *Human Reproductive Technologies and the Law.* See paragraphs 146 to 162, and 394.

6.17 However, the Government would welcome views on lowering the age at which donor conceived people may seek this information from the HFEA's register from 18 to 16.

6.18 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.

Information for civil partners

6.19 The current wording of the HFE Act makes clear that information from the HFEA's register may be sought by a person who believes that he or she was conceived as a result of treatment involving gamete or embryo donation to discover whether that person is related to someone that he or she intends to marry.

6.20 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.

Information about offspring for donors

6.21 The House of Commons Science and Technology Committee sympathised with the view that if children born following donor insemination have a right to know their genetic parents, then donors similarly have some rights to non-identifying information about children born as a result of their donation. This could include information such as the number of children born as a result of the donation, and their sex.

6.22 The HFEA has advised licensed clinics that information may be disclosed to donors as long as it does not identify the children born or the child's legal parents.

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

Information about siblings

6.24 The current legal provisions give people born as a result of donation rights of access to information about their donor. The law does not, however, explicitly address access by donor-conceived people to information about other people born as a result of treatment using the gametes of the same donor (i.e. their genetic half-siblings). Nor does the Act allow the natural child of a donor to find out about half-brothers or sisters conceived as a result of their parent's donation (or vice versa).

6.25 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?

6.26 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?

Parents' responsibility to tell children if they were donor-conceived

6.27 Parliament recently agreed to regulations which remove the anonymity of donors (who register from 1 April 2005), so that children conceived as a result of gamete or embryo donation can obtain information about their genetic origins on reaching 18 years of age should they wish to do so.[38]

6.28 This change recognised the interests of the donor-conceived child in having the opportunity to obtain information about their genetic origins, including the identity of the donor if the child chooses to request this. Information about the donor is recorded by the HFEA on its central database of information and there are strict rules governing access to the information stored there.

6.29 The removal of donor anonymity goes hand in hand with a more open attitude to donor conception, with more parents telling their children that they are donor-conceived. However, there is currently no legal requirement to ensure that children are told that they were conceived through the use of donated gametes or embryos.

6.30 One way to help ensure that donor-conceived children would be told about the manner of their conception would be to add "by donation" to the relevant entry in the birth register. This would mean that the "long" birth certificate, which shows all the information on the birth register, would show this information. A "short" birth certificate is also available which would not include the words "by donation". The Government has not taken a position on this suggestion, and would welcome views.

6.31 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?

38 Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004 No. 1511.

Information for patients and follow-up research

6.32 The HFEA's central data register includes information relating not only to treatments involving donated gametes and embryos, but also information on treatments where the couple's own gametes were used, including cases where treatment did not result in a pregnancy.

6.33 Information collected by the HFEA as part of its regulatory duties is currently used for a range of purposes. These include monitoring the performance of licensed services, and informing licensing decisions. The HFEA has been developing a process of electronic data interchange with licensed centres which will operate via a secure internet connection to enable the rapid transmission of information and reduce the possibility of error. The HFEA has also developed an effective incident alert system to warn clinics, inspectors and the professional bodies about potential or actual dangers to minimise the risk of repetition.

6.34 The HFEA currently makes available a variety of data relating to individual clinics, such as the number of cycles of treatment undertaken and the number of live births. This information is contained in the HFEA's *guide to infertility and directory of clinics*, published as part of the HFEA's general function to provide advice and information to persons who are receiving treatment services or may wish to do so.

6.35 The Government believes that the guide provides a useful resource both for patients and for service providers and commissioners. However, this need not imply that the mandatory collection of patient-identifiable information is necessary, or that a central database of such information should be maintained indefinitely.

6.36 The potential application of the HFEA's data – which now covers a period of 14 years provision of licensed treatments – for the purpose of follow-up research has been the subject of some debate. In particular, whilst the administrative burden on clinics as a result of collecting such data is being reduced through the introduction of electronic data interchange, some stakeholders have argued that the central collection of data on all licensed treatments can only be justified if the data is put to useful purposes such as facilitating research.

6.37 A recent report, *"Assisted reproduction: a safe, sound future"*, published by the Medical Research Council recommended that a monitoring framework for assisted reproduction technologies should be established, based on core data collected by the HFEA and linked to other health records and health outcome data.[39] However, the

39 *Assisted reproduction: a safe, sound future*, Medical Research Council, 2004.

report also noted that the information currently collected centrally by the HFEA may not be sufficient in order to answer the types of research questions that follow-up studies might seek to address. Additional data, such as the unique NHS numbers of parents and children, and information about how pregnancies progress was suggested for consideration for incorporation into the HFEA database.

6.38 The House of Commons Science and Technology Committee has also considered the potential use of the HFEA's data register for research.[40] The Committee made a number of recommendations, including that the *existing* data from the HFEA's register should be applied as far as possible to research studies. However, the Committee was not convinced that the range of data collected by the HFEA should be expanded solely for research purposes. Instead, the Committee proposed that treatment clinics, as a condition of their licence, should each maintain a database in a suitable form which is available for peer reviewed research projects.

6.39 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 accurate and not misleading).

6.40 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?

6.41 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?

Confidentiality requirements

6.42 Both the Medical Research Council report referred to above and the Science and Technology Committee drew attention to the strict confidentiality requirements of the HFE Act, as adversely affecting the conduct of research. The Science and Technology Committee concluded that the confidentiality provisions "are unnecessarily onerous and inconsistent with the widespread use of assisted reproductive technologies".[41] Underlying this conclusion is the assumption that as the use of assisted reproduction technologies has become more common, so any perceived

40 *Human Reproductive Technologies and the Law.* See paragraphs 256 to 264.

41 *Human Reproductive Technologies and the Law*, paragraph 258.

stigma associated with infertility and its treatment has diminished, and therefore the confidentiality provisions of the Act should be revised to be more in line with other areas of medical practice.[42]

6.43 There is a wider concern that the confidentiality provisions of the HFE Act do not only adversely affect the capacity to undertake research, but also hamper activities such as clinical audit and other aspects of patient care. For instance, the fact that a patient has undergone a particular type of fertility treatment may be relevant to antenatal screening. There are currently restrictions that apply even where the patient has given consent to the release of information. In relation to information held by the clinic, a patient can currently only consent to disclosure to a specific person.

6.44 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?

42 *Human Reproductive Technologies and the Law.* However, the Committee notes (in paragraph 262) that there is evidence that confidentiality remains extremely important for people from some ethnic groups who may object to certain forms of fertility treatment.

Section Seven – Surrogacy

7.1 UK legislation addresses surrogacy – where a woman makes a prior arrangement to carry a child with the intention that it will be handed over to someone else at birth – in a finely balanced way. It does not prohibit surrogacy, but it does prohibit the operation of commercial surrogacy agencies and any advertising for a surrogate or willingness to become a surrogate. This balance recognises that there are circumstances where surrogacy may be a reasonable option, for instance where a woman is unable to carry a child herself because she has no womb, but it also recognises the view that it is inappropriate for people to offer or seek financial inducements for surrogacy.

7.2 These provisions are contained in the Surrogacy Arrangements Act 1985. Surrogacy comes within the review of the HFE Act because it often involves assisted reproduction treatment, and the ethical, legal and social issues it brings into consideration are often closely related to those raised by the use of reproductive technologies.

7.3 This section poses questions in relation to the regulation of surrogacy and how far these issues should be dealt with in any revision of the HFE Act.

The Warnock Report

7.4 The Warnock Committee considered that surrogacy presented some of the most difficult problems encountered during their inquiry.[43] The majority view in the Warnock report recommended that the creation and operation of agencies – whether profit or non-profit making – for the purpose of recruiting women to become surrogates or making surrogacy arrangements, should be prohibited. It also recommended that professionals who knowingly assist in the establishment of a surrogate pregnancy should be criminally liable and surrogacy arrangements themselves should be illegal and unenforceable contracts.

7.5 By contrast, a minority of the Committee believed that public opinion had not yet fully formed on the question of surrogacy, and therefore "the door [should] be left slightly ajar so that surrogacy can be more effectively assessed". The minority

43 The Warnock report. See Section 8 and Expression of Dissent A.

members' recommendations included the licensing of surrogacy agencies, which would only be allowed to operate on a non-profit basis, and would only be accessible via referral from a consultant gynaecologist.

Current law relating to surrogacy

7.6 Shortly after publication of the Warnock report, and in response to public concern about commercial surrogacy, the Government introduced a Bill that became the Surrogacy Arrangements Act 1985. That Act prohibits the operation of commercial surrogacy agencies, and any advertising for a surrogate or of willingness to become a surrogate. It also makes clear that surrogacy agreements are not legally enforceable contracts. This means that a child cannot be taken away from a surrogate mother against her will as a result of a surrogacy agreement, although this does not prevent a court ruling (in accordance with other legislation relating to children, which make the child's interests the paramount consideration) that it would be in the child's best interests to be placed elsewhere.

7.7 The HFE Act also contains provisions to enable the intending parents of a child born to a surrogate to obtain a parental order in certain circumstances.[44] The parental order, a form of 'fast-track' adoption, has the effect of removing parental rights from the surrogate mother and reassigning them to the intending parents (generally known as the 'commissioning couple'). One of the conditions for obtaining a parental order is that only 'reasonable expenses' have been paid to the surrogate unless authorised by the court making the parental order. Around 50 parental orders are made each year resulting from surrogacy arrangements.

7.8 The HFEA's Code of Practice includes guidance on surrogacy arrangements that involve licensed treatment services.[45] This guidance covers special considerations in respect of assessing the welfare of the child, information about the requirements for obtaining parental orders, and makes clear that:

> *"treatment centres are expected to consider the use of surrogate pregnancy only where the commissioning mother is unable for physical or other medical reasons to carry a child or where her health may be impaired by doing so."*

Therefore surrogacy arrangements involving licensed services cannot be undertaken on the basis of convenience or for any other reason than on medical or health grounds.

44 Issues around legal parenthood, including the circumstances in which parental orders can be obtained, are considered further in Section 8.

45 HFEA, Code of Practice, 6th Edition, paragraph 3.17.

7.9 The HFEA's *guide to infertility and directory of clinics 2005/06* lists 33 licensed centres prepared to assist, through the provision of licensed treatment, in establishing a surrogate pregnancy.

1997/ 98 Review of payments and regulation ("the Brazier Report")

7.10 In June 1997, Health Ministers commissioned a review of certain aspects of surrogacy arrangements, chaired by Professor Margaret Brazier. The terms of reference of the review required the review team to consider whether payments, including expenses, should continue to be made to surrogate mothers: whether a recognised body or bodies should regulate such arrangements: and if changes were required as a result to the Surrogacy Arrangements Act 1985 and the HFE Act.

7.11 The report of the review team (referred to as the "Brazier Report")[46] made a number of recommendations, including:

- payments to surrogate mothers should be expressly limited to actual expenses occasioned by the pregnancy, and that what constitutes expenses should be defined in law
- payments to surrogates other than expenses would result in ineligibility for parental orders
- agencies involved in surrogacy arrangements should operate only on a non-profit-making basis, and should have to be registered with the Department of Health
- a binding code of practice setting out minimum standards for surrogacy arrangements should be drawn up by the UK Health Departments, the HFEA and other interested bodies (covering matters such as the age of the surrogate)
- a new Surrogacy Act to give effect to the above recommendations.

The House of Commons Science and Technology Committee Review

7.12 The House of Commons Science and Technology Committee considered the need to review the regulation of surrogacy arrangements in its recent report on human reproductive technologies.[47]

46 Surrogacy: Review for Health Ministers of Current Arrangements for Payments and Regulation, Report of the Review Team. Cm 4068, October 1998.

47 *Human Reproductive Technologies and the Law.* See paragraphs 310 to 312.

7.13 The Committee recommended that the Government should include within its review of the HFE Act an assessment of surrogacy arrangements, taking the Brazier Report as a starting point and considering what developments there have been since 1998 (when the Report was published). The Committee further recommended that consideration should be given to introducing separate legislation covering surrogacy.

7.14 In response to the Committee the Government has agreed to consider the need to review surrogacy arrangements and is therefore keen to gauge public and professional opinions on what, if any, changes may be needed to the law and regulation as it relates to surrogacy.

Changes since the Warnock and Brazier Reports

7.15 Whereas the majority opinion of the Warnock Committee, writing in the early 1980's, found that the weight of public opinion was against the practice of surrogacy, attitudes towards the acceptability of surrogacy may have changed over time. There have been relevant changes in the law, regulation and professional guidance on surrogacy since the Warnock Committee, and some research has been undertaken.[48]

7.16 Given legal and other developments since surrogacy arrangements were last reviewed, the questions posed below are intended to elicit views on whether the current review of the HFE Act should attempt to alter the current legal balance regarding surrogacy, and if so, how.

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

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

7.19 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?

48 A longitudinal study of families created through surrogacy is being conducted by Professor Susan Golombok et al, at City University, London involving 37 surrogacy families. The conclusion of the study to date is that surrogacy does not appear to impact negatively on parenting or child development in families with 2-year old children. See Surrogacy families: parental functioning, parent-child relationships and children's psychological development at age 2, Golombok et al, Journal of Child Psychology and Psychiatry.

Section Eight – Status and legal parenthood

8.1 The HFE Act embodied significant changes to the law about the legitimacy of children and the rights and responsibilities of parents.[49] Four sections of the Act deal with matters such as the meaning of "father" and "mother" in relation to children born as a result of assisted reproduction, and also provide a mechanism for re-assigning legal parenthood following a surrogacy arrangement. These sections are grouped in the Act under the heading "status".

8.2 The status provisions of the Act are important as they deal with issues which may be vital to a person's sense of identity as well as distributing individual rights affecting matters such as inheritance.

8.3 This section of the consultation document considers whether changes are necessary to the status provisions of the HFE Act, particularly in view of recent legislation on civil partnership.

The Warnock Committee's recommendations

8.4 The Warnock Committee recommended that a child conceived through the use of donor sperm should be regarded as the legitimate child of its mother and her husband where they had both consented to the treatment (and the husband's consent should be presumed unless the contrary was proved). The intention was to remove a legal distinction between legitimate and illegitimate children, and to give both parents equal rights in relation to the child. The Committee further recommended, as a result of this change, that the sperm donor should have no legal rights or duties in relation to the child.

8.5 Further, the Warnock Committee recommended that the husband should lawfully be able to be registered as the father of the child, although the Committee also thought that consideration should be given to enabling parents to add "by donation" to the birth record if they so wished.

49 The HFE Act followed and extended the provision in the Family Law Reform Act 1987 that enabled a child born to a married woman via donor insemination to be treated as the child of the marriage. This provision came into effect in April 1988.

8.6 The Committee also considered the situation involving egg donation, concluding that the birth mother of the child should be regarded as the legal mother in all circumstances, and the egg donor should have no legal rights or duties in relation to the child. The Committee's recommendations about legitimacy and legal parenthood in cases of embryo donation were the same as those for sperm and egg donation.[50]

The status provisions of the HFE Act

8.7 After public consultation following the Warnock report, the HFE Act introduced changes broadly in line with the Warnock Committee's recommendations.

8.8 The HFE Act as it stands provides, in sections 27 and 28,[51] that:

- the birth mother is always treated as the legal mother of the child
- where donor sperm or a donated embryo are used and the woman is married, her husband is treated as the legal father of the child, unless it is shown that he did not consent to the treatment[52]
- where donor sperm or a donated embryo are used and the woman is unmarried, but was being treated together with a man by a licensed treatment service, that man is treated as the legal father of the child.

8.9 Section 28(6) makes clear that:

- a sperm donor is not to be treated as the father of the child
- a deceased man whose sperm (or an embryo created with it) is used after his death is not to be treated as the father of the child.[53]

8.10 Section 30 of the Act enables married couples to apply for a parental order – a court order providing for a child to be treated in law as the child of the couple – in certain circumstances. The effect of this section is to enable parental rights and responsibilities to be re-assigned following the birth of a child as the result of a surrogacy arrangement.[54] The necessary conditions for the making of a parental order include:

50 The Warnock report, paragraphs 6.8 and 7.6.

51 Section 29 of the HFE Act defines the effect of legal treatment as father and mother as including all purposes other than succession to any dignities, titles of honour, coats of arms and associated properties as described in that section.

52 Section 28(5) of the HFE Act refers to a common law presumption that the husband is the legal father. Therefore in order not to be treated as the child's legal father, the husband would need to show that he did not consent to his wife's treatment and also rebut the common law presumption of paternity.

53 Except for the purpose of birth registration, in accordance with the procedure set out in the Human Fertilisation and Embryology (Deceased Fathers) Act.

54 Following a parental order, the child's birth is re-registered with the names of the couple in place of those of the birth parents.

- the gametes of one or both of the couple must have resulted in the child's conception
- the couple must be at least 18 years of age
- one or both of them must be domiciled in the UK (or the Channel Islands or the Isle of Man)
- the parental order must be applied for within six months of the birth
- no money or other benefit other than reasonable expenses must have been given or received, unless authorised by the court.

Possible changes to the current legal position

8.11 The current provisions of the HFE Act deal with issues of status and legal parenthood in what are likely to remain the most common circumstances found in cases of assisted reproduction. In circumstances not addressed by the HFE Act the resolution of status issues may be dependent on an alternative legal process. Generally speaking, the process of adoption is able to provide an alternative legal process in most cases. However, the Government is aware of arguments that differential treatment in law of different family forms could disadvantage children born in those circumstances.

8.12 The HFE Act is framed in terms of heterosexual couples receiving assisted reproduction treatment. In undertaking this review of the HFE Act, the Government intends to consider the extent to which changes may be needed to better recognise the wider range of people who seek and receive assisted reproduction treatment in the 21st century.

8.13 Other relevant legal changes have occurred since the HFE Act was passed, including the legal recognition of civil partnerships, and also the ability of an unmarried couple to acquire joint parental responsibility for a child through registering the child's birth together. Views are therefore sought on the issues below.

Married and unmarried couples

8.14 The provisions of section 28 described above clearly distinguish between married and unmarried couples.[55] Whereas a married man can be treated as the child's father regardless of where treatment took place, an unmarried couple must be receiving treatment together at an HFEA-licensed clinic (and therefore only in the UK).

55 There is also a common law presumption of legitimacy which presumes a married man to be the father of his wife's children unless there is evidence on the balance of probabilities that this is not the case. This presumption applies whether or not assisted conception is involved.

8.15 Although the Government recognises that this potentially discriminates unfairly against unmarried couples, it is difficult to see how unmarried couples could be treated in the same way as married couples in section 28 given the lack of legal definition of an unmarried couple.

8.16 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?

8.17 Similarly, parental orders following surrogacy arrangements can only currently be made in favour of married couples, subject to the criteria in section 30 of the HFE Act mentioned in paragraph 8.10 above.

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

Civil partnerships

8.19 The Civil Partnership Act 2004 received Royal Assent on 18 November 2004. The Government announced on 21 February that the Act would come into force on 5 December 2005.[56] The Act creates a new legal relationship of civil partnership, which two people of the same sex can form by registering as civil partners of each other.[57]

8.20 Important rights and responsibilities will flow from forming a civil partnership, including:

- a duty to provide reasonable maintenance for a civil partner and any children of the family
- civil partners to be assessed in the same way as spouses for child support
- recognition under intestacy rules
- recognition for immigration and nationality purposes.

8.21 It is the Government's policy to provide same-sex couples who form a civil partnership with parity of treatment in a wide range of legal matters with opposite-sex couples who enter into a marriage.

56 This will allow the first civil partnerships under the standard procedure to be formed on 21 December 2005.

57 Certain overseas relationships registered abroad may also be treated as civil partnerships under the Civil Partnership Act 2004.

8.22 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.**

8.23 As described above (in paragraph 8.14), the HFE Act provides that an *unmarried* man is the legal father of a child born as a result of treatment using donated gametes or embryos where he and the child's mother were receiving treatment together at a licensed clinic. The Act does not contain a similar provision for same-sex couples who do not form a civil partnership.

8.24 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?

Section Nine – Research

9.1 One of the primary functions of the HFE Act is to regulate research on human embryos. Embryo research is permitted under the Act subject to statutory restrictions and strict control by the HFEA. This position reflects considerable public and parliamentary debate over many years.

9.2 Research involving embryos remains one of the most controversial areas dealt with by the HFE Act, with deeply held views reflecting fundamental moral beliefs on all sides. In passing the HFE Act, Parliament decided to allow embryo research subject to statutory controls, with Members of Parliament voting according to conscience and the Government adopting a neutral stance. In 2001, Parliament voted to extend the purposes for which embryo research could be undertaken, again on a 'free vote'.

9.3 In announcing the review of the HFE Act, the Government made clear that it does not intend to open up the most fundamental aspects of the Act, or those aspects that have been extensively and conclusively debated in recent years. Parliament has taken the view that the creation and use of embryos for research, subject to appropriate restrictions and safeguards, should be allowed to take place. This section therefore considers research issues from that point onwards, such as the specific restrictions in the Act that relate to research, and how approval and oversight mechanisms should be structured.

The Warnock Report

9.4 The Warnock Committee gave extensive consideration to arguments for and against research involving embryos.[58] A majority of its members recommended that while the human embryo should be afforded some protection in law, research should be permitted subject to stringent controls and monitoring.

9.5 This view took into account the fact that the advances in the treatment of infertility that the Committee was asked to examine could not have taken place without research using embryos, and that such research was necessary if advances in treatment and medical knowledge were to continue. It was recognised that strict controls were essential to safeguard the public interest and to allay widespread anxiety, and in particular to avoid a situation where embryos were used frivolously or unnecessarily.

58 The Warnock report. See especially section 11, and expressions of dissent B and C.

The research provisions of the HFE Act

9.6 Following public consultation, the Government framed its proposals for legislation taking account of the nature and diversity of the views held in relation to embryo research, and to ensure that those views were properly debated. Parliament was therefore presented with a choice between alternative sets of draft legal clauses to permit or to prohibit embryo research. The HFE Act sets out the activities which may be authorised by the HFEA through the grant of a licence to undertake a project of research. Research centres must apply to the HFEA for separate licences in respect of each separate research project.

9.7 The HFEA may only grant licences for research projects if it appears (to the HFEA) that the activity is necessary or desirable for one or more of the research purposes listed in the Act. The HFEA cannot grant a research licence using human embryos unless it is satisfied that the use of human embryos is necessary for the purposes of the research.

9.8 The HFE Act allows the purposes for which embryo research may be permitted under licence to be extended with the agreement of Parliament. Regulations were passed in 2001 which extended the list of research purposes primarily with the intention to increase understanding about human diseases and disorders and their cell-based treatments. This followed the Government's acceptance of the conclusions of the Chief Medical Officer's Expert Group Report "Stem Cell Research: Medical Progress with Responsibility".[59]

9.9 The extended list of purposes for which research involving embryos may be permitted is as follows:

- promoting advances in the treatment of infertility
- increasing knowledge about the causes of congenital disease
- increasing knowledge about the causes of miscarriages
- developing more effective techniques of contraception
- developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation
- increasing knowledge about the development of embryos
- increasing knowledge about serious disease, or

59 Published in December 1998 by the Department of Health. See also the Government's response published by The Stationery Office as Cm 4833.

- enabling any such knowledge to be applied in developing treatments for serious disease.

9.10 There are, however, a number of activities which cannot be authorised by a licence to undertake research, and are therefore prohibited. These are:

- keeping or using an embryo after the appearance of the primitive streak (taken to be not later than the end of a period of 14 days beginning with the day when the gametes are mixed)
- placing a human embryo in an animal
- 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
- altering the genetic structure of any cell while it forms part of an embryo.

9.11 In addition, Parliament can set out in regulations any further circumstances in which keeping or using an embryo is prohibited.

Issues for the review of the HFE Act

9.12 The Government does not intend to re-open the fundamental issue of the permissibility of research involving embryos. However, the current review of the Act will cover the parameters of legitimate research – the activities which may lawfully be carried out – and the mechanisms through which they may be authorised and overseen.

9.13 Several of these issues were considered in the House of Commons Science and Technology Committee's recent report on human reproductive technologies and the law. The Committee made several recommendations about both the specific prohibitions in the HFE Act, and the system of ethical oversight imposed through regulation.[60]

The 14 day time limit

9.14 The time limit imposed by the HFE Act on keeping or using an embryo outside the body relates to the appearance of a feature known as the primitive streak, which can be considered as marking the beginning of individual development of the embryo, and the first sign of the development of a nervous system.

60 See in particular recommendations 4, 7-16, 59, 83, 100 and 104.

9.15 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.

Cell nuclear replacement

9.16 The technique of cell nuclear replacement (CNR) involves taking the nucleus of one cell and placing it in another cell that has had its nucleus removed. This could involve the use of bodily cells, reproductive cells (gametes and embryos) or a combination of both.

9.17 Cell nuclear replacement is allowed under HFEA licence in order to *create* embryos for research only. This process – known as therapeutic cloning – involves the use of a nucleus from an adult cell and an egg that has had its nucleus removed. These embryos can be used, for example, to derive stem cells for research into treatments for serious diseases, such as Parkinson's Disease.

9.18 The use of CNR to create embryos has been extensively debated over recent years. The House of Lords Select Committee on Stem Cell Research, reporting in 2002, concluded that there was a powerful case for the use of CNR, subject to strict regulation, as a research tool to enable other cell-based therapies to be developed.

9.19 An embryo created by CNR cannot be used in fertility treatment as the Reproductive Cloning Act 2001 prohibits placing an embryo in a woman if it has been created other than by fertilisation.

9.20 The HFE Act also currently prohibits 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. This means that, although the law allows the *creation* of embryos for research by the process of CNR, the use of CNR techniques on embryos *once they have been created* is prohibited.

9.21 The use of CNR on embryos for research was recently considered by the House of Commons Science and Technology Committee.[61] In particular, the Committee considered the use of CNR for research into mitochondrial disorders which are known to cause more than fifty inherited metabolic diseases.[62] As these problems

61 *Human Reproductive Technologies and the Law.* See recommendation 14.

62 Mitochondria are small energy producing structures in the cytoplasm of every cell, which are only inherited from the mother. (Source: The Chief Medical Officer's Expert Group Report *Stem Cell Research: Medical Progress with Responsibility*, paragraph 220).

occur in the outer part of a cell, rather than the nucleus, CNR could (in theory) be used to put an otherwise 'healthy' nucleus into a cell which is free from mitochondrial disorders and therefore result in a 'healthy' embryo. The law does not currently prohibit this type of research being undertaken on human eggs in order to create an egg free from mitochondrial disorders. The Committee concluded that there was no reason to distinguish in law between the use of CNR on eggs and on embryos for the purposes of research into mitochondrial diseases as the aim would be the same in both cases.

9.22 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.

9.23 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.

Altering the genetic structure of an embryo

9.24 The HFE Act prohibits altering the genetic structure of any cell while it forms part of an embryo. This is currently an absolute ban with regard to assisted reproduction treatment, and section 5 considered what, if any, change should be made to this position.

9.25 However, with regard to research, the Act enables Parliament to pass regulations to permit this activity under licence from the HFEA. To date, no regulations under this section of the Act have been made.[63]

9.26 This restriction overlaps with that discussed above insofar as replacing the nucleus of an embryo, or taking the nucleus of an embryo and placing it in another cell, is altering the embryo's genetic structure.

9.27 There could be several reasons for undertaking research involving altering the genetic structure of an embryo. It could, for example, aim to develop therapies to prevent the transmission of harmful gene variations to subsequent generations. If it could be done safely, such therapies might be a way of repairing gene defects before clinical manifestations and would also spare descendants the burden of serious genetic diseases. The development of such therapies would, however, require extremely thorough research and testing.

63 See HFE Act schedule 2,(3),(3).

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

Human-animal hybrids and chimeras

9.29 The HFE Act makes clear that a human embryo cannot be placed in an animal, or vice-versa, and that human and animal gametes cannot be mixed other than in very specific circumstances. Only a human embryo, or human gametes, may be placed in a woman. These provisions reflected public disquiet about the prospect of creating hybrid embryos (for example by the fertilisation of a human egg with the sperm of another species), or "chimera" embryos (for example by fusion of the cells of a human embryo with cells from the embryo of another species).[64]

9.30 The Government has heard no compelling evidence that there is any reason to remove the prohibition on placing human embryos in animals (or vice-versa) and we have no intention of changing this position.

9.31 However, the Government is aware of arguments that there may be benefits in the research use of embryos created through the combination of human and animal material. At present the mixing of human and animal gametes is only allowed (under licence) for testing the fertility or normality of human sperm, and the result of the mixed gametes must be destroyed when the test is complete and definitely no later than the two cell stage. Other human-animal cell fusion products have been widely used in biosciences research for many years, for example in the development of treatments for some types of breast cancer.

9.32 Reasons for wanting to create hybrid or chimera embryos for research could include:

- to test the capacity of embryonic stem cells to differentiate into a range of bodily cell types, as part of research into the treatment of serious diseases
- to derive human embryonic stem cells, thereby circumventing the shortage of good quality human eggs available for research.

9.33 The House of Commons Science and Technology Committee has recommended[65] that new legislation should:

- define the nature of hybrids and chimeras

64 For the purposes of this consultation a 'chimera' is a human or animal embryo into which other human or animal genetic material has been inserted; a 'hybrid' is a human or animal egg into which human or animal genetic material has been inserted other than the normal reproductive cells.

65 *Human Reproductive Technologies and the Law.* See recommendation 9.

- make their creation legal for research purposes (provided they are destroyed in line with the 14 day rule)
- prohibit their implantation in a woman.

9.34 The Committee recognised that there are strongly held views both for and against this proposal, ranging from revulsion in some quarters to arguments that the creation and destruction of such creations pose fewer ethical problems than the creation and destruction of purely human embryos.

9.35 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).

The purposes for which research may be permitted

9.36 As outlined in paragraph 9.9 above, the HFE Act lists those legitimate purposes for which research may be licensed by the HFEA. Parliament extended this list of purposes in 2001 through regulations, primarily in response to potential developments in stem cell research.

9.37 The Government is aware of concerns that the list of purposes, while allowing applied research, may not appear to allow some forms of basic research which could be a necessary precursor of more specialised research into serious diseases. The Government has previously made clear that it is confident that basic research is permissible under the current list of legitimate research purposes.

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

Approval of research projects

9.39 The current system for the approval and licensing of a research project using embryos involves several elements. Before the HFEA approves a research licence, it is expected that each research project will be referred to a properly constituted ethics committee for approval. Proposals will also be submitted to appropriate academic referees chosen by the HFEA for peer review.

9.40 The Government is aware of arguments that this system of approval is overly bureaucratic, and may involve duplication of effort between national and local bodies. One suggestion is that the processes of peer review and approval by a local research ethics committee could replace consideration of research projects by the HFEA, and

furthermore would dispense with the need for legally defined research purposes. However the Government has rejected this approach due to reservations about the consistency of decision-making, expertise available, and the clarity of responsibilities in such a system.

9.41 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.

Use of, and payments for, gametes in research

9.42 The HFE Act contains some restrictions on the use of gametes (sperm and egg) but does not generally seek to regulate their use in research. Use of gametes to create an embryo is a criminal offence without a licence from the HFEA, and the Act also prohibits the mixing of human and animal gametes and placing non-human gametes in a woman. Research use of gametes per se, not involving the creation of embryos or other prohibited activities, can therefore fall outside of the scope of regulation under the HFE Act.

9.43 The Government is, in particular, aware of concerns that the law does not prevent payments being made for the supply of gametes to be used in research (in circumstances where a licence is not required), and that this could lead to people being exploited or taking inappropriate risks. (See also Section Four, paragraphs 4.46 and 4.47.)

9.44 Medical practitioners are, however, expected to follow the guidance published by the General Medical Council, *Research: the Role and Responsibilities of Doctors*, published in 2002. This makes clear that payments should not be offered at a level which could induce research participants to take risks that they otherwise would not take. Further, research must be conducted in accordance with the Department of Health's Research Governance Framework, which includes referral to an independent research ethics committee.[66]

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

66 Available at www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/fs/en

Creation of embryos for therapeutic purposes

9.46 Whereas research using embryos for the purpose of developing treatments for serious diseases is permissible under the HFE Act, the creation of embryos for the direct therapeutic benefit of a patient would be prevented by the wording of the Act in relation to licences. This is because the current wording of the Act sees the creation of an embryo for *treatment purposes* as being for the purpose of assisting a women to carry children. This means that while an embryo could be created for a project of *research* involving experimental therapy on a patient, the same activity could not be undertaken under a treatment licence. Therefore, in effect, the therapy in question would be prevented once its effectiveness had been proven through research.

9.47 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).

Section Ten – Regulatory Authority for Tissue and Embryos (RATE)

10.1 In 2004 the Department of Health carried out a review of its 'arm's length bodies' – those national organisations sponsored by the Department and undertaking executive (rather than advisory only) functions, at "arm's length" from Government. These bodies form a network of organisations created to regulate the healthcare system, improve standards, protect public welfare and support local services. The review was part of a wider programme to improve efficiency and cut bureaucracy. The conclusions of the review were published in July 2004 in the report *Reconfiguring the Department of Health's Arm's Length Bodies*, and included proposals to reduce the number of arm's length bodies from 38 to 20, with substantial reductions in the overall cost of the sector.[67]

10.2 One of the conclusions of the arm's length body review was the proposal to replace, by April 2008, the Human Fertilisation and Embryology Authority and the Human Tissue Authority with a single body with responsibilities across the range of human tissues and cells, including blood and organs.[68]

10.3 The new body will be called the Regulatory Authority for Tissue and Embryos (RATE) and will replace the HFEA and HTA in their entirety. It will become the single 'competent authority' responsible at national level for oversight of the quality and safety standards required as a result of the EU Tissue Directive. It is proposed that it should also become the competent authority for the EU Blood Directive and take on certain regulatory functions from NHS Blood and Transplant. The creation of RATE will require primary legislation. This section gives more detail on the Government's proposals for the new regulatory body.

67 Available at www.dh.gov.uk/PublicationsAndStatistics/fs/en or from the publications orderline 08701 555 455, reference 40378. This document refers to the Regulatory Authority for Fertility and Tissues (RAFT), however the name RATE is now proposed to prevent confusion with the Restoration of Appearance and Function Trust.

68 RATE will replace the UK role of the HFEA and the England, Wales and Northern Ireland role of the HTA. The current role of the HTA is defined in the Human Tissue Act 2004. See www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/Tissue/TissueGeneralInformation/fs/en

RATE – composition, functions and accountability

Composition

10.4 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.

Functions

10.5 The exact functions of RATE with regard to the regulation of assisted reproductive technologies will depend, in part, on the outcome of other issues covered in this public consultation exercise. However, 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**
- to support its licensing function, **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**

10.6 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.

Accountability

10.7 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.**

Role of the professional bodies

10.8 The House of Commons Science and Technology Committee has recommended that the regulator should be supported by an advisory body for technical standards comprising the relevant professional bodies under the auspices of the Royal College of Obstetricians and Gynaecologists and the Royal College of Pathologists.[69] The Committee recognised that any such standards would need to be consistent with the quality and safety requirements of the EU Tissue Directive, which will be implemented in UK law.

10.9 The Government welcomes the proactive role of the professional bodies to date in promoting best practice and maintaining high standards. The professional bodies continue to play an important part in informing statutory requirements and guidance through the HFEA's Code of Practice.

10.10 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.

Ensuring compliance

10.11 As a licensing authority, RATE will ultimately be able to revoke or vary licences if necessary in response to breaches of regulation. It will also be able to impose licence conditions and make directions which are binding on licence holders. However, there may be circumstances in which a less serious breach of regulation may not justify the withdrawal of a licence, and it is argued that less severe sanctions would be appropriate.

10.12 The House of Commons Science and Technology Committee considered this issue and concluded that a wider range of sanctions should be available, but that they should operate in an environment which encourages the improvement of standards and systems.[70]

69 *Human Reproductive Technologies and the Law*. See recommendation 100.

70 *Human Reproductive Technologies and the Law*. See paragraphs 185 to 187.

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

10.14 The Science and Technology Committee also considered the penalties that apply to the offences in the HFE Act, and in particular the maximum penalty of ten years imprisonment for certain offences. The Committee considered this penalty to be unduly harsh.[71] The ten year penalty currently applies to:

- placing a non-human embryo or gametes in a woman
- placing a human embryo in a animal
- mixing animal and human gametes
- keeping or using a human embryo outside the body after 14 days development.

10.15 Ten years imprisonment is also the maximum penalty under the Human Reproductive Cloning Act for placing in a woman a human embryo created otherwise than by fertilisation.

10.16 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?

71 *Human Reproductive Technologies and the Law.* See paragraph 183.

Partial Regulatory Impact Assessment

Title

R1.1 Review of the Human Fertilisation and Embryology Act.

Purpose and intended effect

R1.2 The Government's objective in reviewing the Human Fertilisation and Embryology Act is to ensure that the law remains effective and fit for purpose in the 21st century. The review takes account of factors such as:

- the development of new technologies and procedures
- international developments in standards
- the need to ensure the effectiveness of regulation.

R1.3 In reviewing the law, the Government has regard to the principles of good regulation – proportionality, accountability, consistency, transparency, and targeting. Respondents may wish to consider the extent to which these principles are upheld both in relation to the Government's proposals, and their own responses.

Options, benefits and costs

R1.4 This consultation document predominantly asks questions rather than makes proposals. In some instances the Government seeks views on specified options, in others it is for respondents to make suggestions and therefore the range of potential options is correspondingly broad.

R1.5 Assessment of the potential regulatory impact of different options will be further developed following consultation, as proposals emerge. The purpose of this section is, at this stage, to draw attention to those issues where options could include a new or significantly increased (or reduced) regulatory burden.

R1.6 Assessing the impact of regulatory measures in this area is, however, not straightforward. It may be impossible, or inappropriate, to quantify benefits and costs solely in monetary terms. In some cases, questions are posed based on

speculation about future developments – and respondents may wish to comment on the possible 'opportunity costs' (opportunities foregone) under different regulatory options.

R1.7 Another factor is that many of the issues considered in this consultation relate to whether something should continue to be required by legislation or should be for good practice or professional guidance, such as the provision of appropriate information to patients. Therefore, it may be the case that if a legal requirement were removed, the activity in question would carry on at much the same level and hence the financial impact of the proposal would be negligible.

Potential new, increased or reduced regulatory impacts

Regulation of fresh gametes

R1.8 Regulation of 'fresh' gametes (paragraphs 2.33 to 2.37). Options are presented which include limiting regulation only to measures required by European legislation (safety and quality matters only), or bringing regulation of fresh gametes into line with the full requirements of the HFE Act where relevant. The nearest comparison of the possible costs of 'full' regulatory oversight here are the fees levied on clinics providing donor insemination – currently £51 per donor insemination treatment cycle – although it is unlikely that all the regulatory requirements applicable to donor insemination would be relevant. Paragraphs 4.10 to 4.11 ask whether requirements for written consent should extend to procedures involving 'fresh' gametes.

R1.9 Internet-based donor sperm services (paragraphs 2.38 to 2.42). Options are presented which include prohibition of these services, regulation of safety and quality matters only, or regulation in line with other donor insemination services.

Regulation of screening and selection

R1.10 Paragraphs 5.14 to 5.23 invite views on the future regulation of embryo screening and selection, including the option that this would be a matter for clinicians and patients within legally-defined limits, rather than for the regulator. In terms of direct costs to treatment centres, if this option was selected, there would be a saving in terms of the cost incurred through the regulator's approval process (i.e. HFEA licensing) where this is currently necessary. However, it is possible that such a saving would be offset by a need for clinicians to seek legal advice on whether they are operating within the law. This would depend on how revised law was worded. Paragraphs 5.24 to 5.27 invite views on what statutory controls should apply to screening and selection of gametes.

Centrally collected information and confidentiality

R1.11 Section 6 considers mandatory collection of information and the confidentiality provisions of the Act. Views are sought in particular on the scope of centrally collected information, and a reduction would produce direct savings for those making central returns.[72] Various questions are posed in section 6 about making centrally collected information more accessible to individuals, and to researchers, subject to safeguards. Servicing those requests would have cost implications for the regulator and treatment centres, offset by potential benefits to individuals and to wider society. Potential benefits include safer and more effective assisted reproduction treatments, as well as improved care in other settings due to improved record linkage.

Surrogacy

R1.12 Section 7 invites views on regulation of surrogacy arrangements, including whether implementation of the recommendations of the earlier 'Brazier' review would be appropriate. This would require agencies involved in surrogacy arrangements to register with an appropriate body. We are currently aware of two (non-profit making) agencies operating in this field. They would incur new costs if registration were to be required in future.

Status and legal parenthood

R1.13 Section 8 (status provisions and legal parenthood) poses questions primarily about the circumstances in which legal parenthood should automatically be gained in cases of assisted reproduction, or through the process of application for a parental order. Clearly changes to the status provisions of the Act would have potential benefits for those families affected. For example, where parenthood was acquired automatically, there would be no need for a separate judicial process.

RATE and charges for private IVF treatment

R1.14 Section 10 details the Government's proposal to replace the Human Fertilisation and Embryology Authority and the Human Tissue Authority with a single regulator called the Regulatory Authority for Tissue and Embryos (RATE). This proposal follows the Department of Health's review of its "arm's length bodies", and is itself part of a wider programme to improve efficiency and reduce bureaucracy. Paragraphs 2.48 and 2.49 ask whether the regulator should have a

72 However, the HFEA's introduction of electronic data interchange will also drive down the costs of central collection of data.

role in relation to prices charged for privately-funded treatment. This would be a new role for a regulator in this area, with a range of potential effects on the market for services.

Conclusion

R1.15 Assessment of the potential regulatory impact of the review of the HFE Act will be developed further as proposals emerge.

R1.16 **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.**

Annex A – Outline of the Human Fertilisation and Embryology Act 1990

A1.1 The scheme of regulation under the HFE Act essentially comprises two elements – a range of prohibitions and permissions, and oversight by an independent statutory regulator. Below is a summary of the main provisions of the Act.

A1.2 The main activities regulated by the HFE Act, which applies to the whole of the United Kingdom, are:

- treatment or research involving the creation, keeping or use of human embryos outside the body
- the storage or donation of human eggs, sperm or embryos.

A1.3 These activities are subject to a system of licensing and inspection by the Human Fertilisation and Embryology Authority (the HFEA).

Prohibitions

A1.4 The HFE Act contains several absolute prohibitions, to which criminal penalties apply. Specific prohibitions in the Act include:

- placing a human embryo in an animal
- placing in a woman any non-human sperm, eggs or embryos
- keeping or using an embryo after 14 days development.

A1.5 In addition, the Human Reproductive Cloning Act 2001 prohibits placing in a woman a human embryo created otherwise than by fertilisation.

Licensable activities

A1.6 The Act also lists activities that can only be carried out if authorised by a licence granted by the HFEA, and it is an offence to carry out licensable activities without a licence.

A1.7 The HFE Act defines the scope of licences which the HFEA is able to grant – broadly these are treatment, storage or research – and the practices which may be authorised under each type of licence. Licences cannot authorise any activity unless it appears to the HFEA to be necessary or desirable for the purpose in question.

A1.8 Licences are issued subject to a range of conditions set out in the HFE Act. These include:

- the keeping of proper records
- compliance with requirements for consent
- taking into account the welfare of any child who may be born as a result of treatment (including the need of that child for a father)
- providing a suitable opportunity for proper counselling on implications, and
- the provision of such relevant information to patients or donors as is proper.

A1.9 The duties of the person under whose supervision the licensed activities are carried on (the 'person responsible') are also specified in the Act. These include ensuring that the conditions of the licence are complied with.

The Human Fertilisation and Embryology Authority (HFEA)

A1.10 The HFE Act sets out the composition, role and remit of the HFEA, including the requirement for a lay chairperson and a majority of lay members. It also requires the HFEA to maintain a code of practice giving guidance about the proper conduct of licensed activities, and of the person responsible. Compliance with the code may be taken into account in decisions to grant or revoke licences. The HFEA's Code of Practice is subject to the approval of the Secretary of State for Health and must be laid before Parliament.

A1.11 Besides its functions in relation to licences and the Code of Practice, the HFEA also has some general functions defined in law. These are broadly:

- to keep under review information about embryos and activities governed by the HFE Act, and advise the Secretary of State for Health on those matters if asked to do so
- to provide information to the public about the provision of licensed services
- to provide advice and information, as it considers appropriate, to patients and practitioners.

A1.12 The HFEA is also required to maintain a register of information relating to the provision of treatment services to identifiable individuals and the children born as a result, including the use of donated sperm, eggs and embryos. There are detailed rules set out in the HFE Act governing access to this information.

Legal status provisions

A1.13 The HFE Act also contains provisions which determine the legal status of "father" and "mother" for persons undergoing assisted reproduction treatment involving donated gametes (sperm and eggs) or embryos, and enables the courts to make orders which reassign parental responsibility in certain circumstances involving surrogacy arrangements.

Subsequent legislation[73]

- The Human Fertilisation and Embryology (Statutory Storage Period) Regulations 1991 No. 1540
- The Human Fertilisation and Embryology (Licence Committee and Appeals) Regulations 1991 No. 1889
- The Human Fertilisation and Embryology (Special Exemptions) Regulations 1991 No. 1588
- The Parental Orders (Human Fertilisation and Embryology) Regulations 1994 No. 2767
- The Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996 No. 375
- The Human Fertilisation and Embryology (Research Purposes) Regulations 2001 No. 188
- The Human Reproductive Cloning Act 2001 c.23
- The Human Fertilisation and Embryology (Deceased Fathers) Act 2003 c.24
- Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004 No. 1511.

73 These are available online at www.hmso.gov.uk or printed copies can be purchased from The Stationery Office.

Annex B – Questions and proposals for consultation

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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

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).

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).

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).

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).

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).

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).

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).

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).

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).

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.

Produced by COI for the Department of Health

269640 1p 3k Aug 05 (LIN)

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