

May 2004

Human Fertilisation and Embryology Authority

Evidence for the Science and Technology Select Committee Inquiry on Human Reproductive Technologies and the Law

Introduction and Summary

1. The HFEA welcomes the opportunity of this Select Committee Inquiry to discuss where Parliament sees the future of reproductive medicine and science in the UK and its regulation. Since we last met the Select Committee in 2002, much has happened, both organisationally for the HFEA and in terms of scientific and medical advances.

- The HFEA has significantly strengthened its regulatory capacity and is now much better equipped to deal with the challenges of reproductive medicine and science than before.
- We are making considerable improvements to our registry function, with much increased reliability and accessibility of our database.
- New regulations permit the use of embryos for stem cell research, giving extra importance to the HFEA's role as a regulator in this field.
- We have sought to be a more publicly accessible and accountable regulator and are taking steps to communicate more effectively with our different stakeholders.
- But, as the Committee's online consultation shows, the area of reproductive technologies remains controversial and a matter of profound public interest. The legislative framework on which the HFEA is based dates back to the Warnock Report of 1984. Almost 20 years after Warnock, it is time to take a fresh look at the 1990 Act and the HFEA is preparing its own advice for the Department of Health on areas it feels are ripe for change.

2. This submission focuses on the four areas of concern flagged up in the Inquiry's terms of reference. We are happy to elaborate on any of these further, particularly at an oral evidence session. We are also able to provide more detailed briefings on any issue that the Committee wishes to focus on.

“Balance between legislation, regulation and reproductive freedom”, the “role of Parliament” and the legislative framework for reproductive technologies:

3. Reproductive science and medicine remains controversial and retains its ability to worry or even shock people. Different, often contradictory, interests and views - including arguments about reproductive freedom, but also about the

protection of embryos, welfare of children, disability, consent, childlessness, the natural order etc - are forcefully expressed by different stakeholders and at times played out in the media.

4. We believe that one of the main reasons for the successful development of reproductive science in this country is that the HFEA is able to undertake robust, evidence-based reviews which bring together scientific and ethical considerations in a way that is both publicly accountable and accessible. Only an independent expert body, at arms length from Government, can offer the necessary combination of flexibility in addressing individual cases and consistency in policy making.

5. Reproductive freedom is an important consideration in the HFEA's decision making about treatments and their availability. But reproductive freedom – in itself a concept that is difficult to define - cannot always and in all circumstances be the paramount consideration, in particular where a couple's wishes might be to the detriment of any children born from a particular treatment.

The recent HFEA decision to reduce the number of embryos per transfer from 3 to 2 is a good example of how sound evidence based policy making can address the tension between notions of reproductive freedom and the patient safety/ child welfare/ public health agenda.

Using data from our Register, backed up by comparisons from the United States, we can demonstrate that, for women in their 30s or below, limiting embryo transfers to a maximum of two makes no real difference to their chances of pregnancy but will reduce the number of triplets or twins. However, for women aged 40 and over transferring three embryos will not usually result in a triplet birth and will slightly improve their chance of becoming pregnant. These findings, together with responses to our consultation exercise on the 6th edition Code of Practice, helped shape a policy that should reduce multiple births without reducing the chances of women giving birth to a single, healthy baby.¹

Looking forward, we will continue to monitor the impact of this and other areas of policy through data submitted to the Register and information obtained during inspections. Further revisions of our policy will be based on this evidence and will have a strong risk focus.

6. The challenges of evolving reproductive medicine raise the question of how conflicting interests are best resolved. Ultimately it is for Parliament to strike the overall balance and to provide the legal framework. The regulatory framework created by the 1990 Act has in general terms responded well to new scientific and medical practice and public concerns, including those that were not foreseen when the Act was passed. But other parts of the Act now seem to be in need of

¹ More information about this policy can be found at:
www.hfea.gov.uk/PressOffice/Backgroundpapers/MultipleBirths

revision, for example the definition of an embryo. There may also be a case for considering the introduction of further regulation-making powers in the Act, for example to give greater flexibility in regulating the treatments that licensed centres can provide.

7. The HFEA policy on pre-implantation genetic diagnostic with HLA tissue-typing and the licence committee decisions concerning two such applications are a case in point. They concern a new and controversial technology that was not foreseen by the legislature in 1990. In 2002, the HFEA received applications for PGD with tissue typing that were ultimately dealt with by its licence committees, within a policy framework determined by the Authority which explored the scientific, legal, medical and ethical issues as they were known at the time. The Authority's discretionary powers have since been confirmed by the Court of Appeal. But this is not the end of the process. We are aware that the policies are controversial and that both the evidence base and public opinions can change. We are therefore conducting a review of our policies on embryo biopsy with tissue typing which we expect to conclude this summer.

The Court of Appeal stated in 2003 (in the so-called Hashmi decision concerning HLA tissue typing and PGD) that, *“Parliament envisaged the possibility or likelihood of future developments (even though it could not know precisely what they would be) and positively intended to bring all such procedures within the sphere of the HFEA, with the exception of those specifically prohibited.”*

We welcome this decision but believe that a wider review of the 1990 Act would provide an opportunity for Parliament to debate, in the light of scientific, medical and social developments over the past 14 years, whether this remains its intention. This renewed political consensus would lead to increased stability for our decision making and would hopefully benefit patients by reducing the likelihood of costly and time consuming judicial reviews.

“Context of national and international legislation and regulation of medical practice and research”

8. The HFEA operates in a regulatory landscape that has changed considerably over the last decade and which continues to change and develop. For example, the patient safety agenda, quality assurance and healthcare inspection - both inside and outside the NHS system - have moved to the fore of health policy (NPSA, the Healthcare Commission, MHRA, GMC, MRC). The HFEA needs to

be responsive to this changing landscape.² We are keen to work collaboratively with other regulators to avoid over- and under-regulation.

9. The EU Tissues and Cells Directive will mean a significant expansion of our role with regard to previously unlicensed practices such as those involving fresh sperm, IUI and GIFT³ (though at present no extra funding from the Department of Health is envisaged). It is the Department of Health's intention (subject to Parliamentary approval) to designate the HFEA as the "competent authority" under the Directive, responsible for licensing anyone handling gametes and embryos. This means a significant expansion of our role. The proposed Human Tissue Authority (HTA) will cover all other tissues and cells, and it will be essential for the HFEA and the HTA to work closely together to ensure the efficient regulation of establishments licensed under the Directive.

10. One development that we need to keep in mind is that with the possibility of de-differentiating and reprogramming cells, the distinction between reproductive and 'normal' tissues might get increasingly blurred. It is important that the HFE Act's definitions enable us to regulate tissues with reproductive capacities whichever way they were created or derived. We would welcome a change to the Act that would allow the Authority to react to these developments as and when they might occur – this means changing at least the definition of 'embryo' and 'gamete'.

11. In our view there is a continued need for stronger safeguards for reproductive uses of human tissues in medicine and research regardless of how the reproductive capacity of a cell or tissue has been achieved. The possibility of creating a new person puts this area into a category of its own, triggering a very particular set of ethical concerns.

12. The EU Tissue Directive introduces a wider emphasis on safety and quality into UK regulation of reproductive technologies. This will impact on the way we conduct our inspections and we are currently examining these implications, for example through discussions with professional bodies about accreditation standards. However, we are already committed to improving patient safety through a wide range of measures. For example, we were internationally the first body to introduce an incident alert system into reproductive medicine and will shortly be launching an international pilot of this approach.

² There might also be a case for revisiting section 8 of the 1990 Act, which defines the general functions of the Authority, in order to define more clearly the regulatory aims of the HFEA.

³ The directive may also require the individual inspection and licensing of transport centres and the 'satellite service' clinics which licensed centres currently provide. This would increase substantially the number of clinics the HFEA has to inspect and license.

The Authority's aim is to minimise duplication and to pool efforts and resources wherever practicable. We are doing this by:

- Working closely with professional bodies and associations linked to assisted reproduction and developing agreed protocols on the conduct of inspections.
- Agreeing a memorandum of understanding with the GMC and working towards similar agreements with other regulatory bodies (such as MHRA and CHAI).
- Close liaison with the HGC through mutual co-optation of members and exchange of information.
- Active involvement in the MRC's development of protocols for the use of stem cells.

Challenges from the “development of new technologies for research and treatment” and “recent changes in ethical and societal attitudes”

13. Science in the area of human embryology, in particular at the interface with genetics, is permanently generating new insights and possibilities. Equally, societal attitudes to assisted conception have changed in some respects since 1990. The fast moving nature of reproductive science and medicine makes a strong case for expert regulation where inspection, regulation, policy and horizon scanning need to go hand in hand in order to facilitate safe and ethically robust research and treatment.

14. We are aware of the need to increase our capacity to engage in systematic horizon scanning. This is identified as a priority in our 2004/5 business plan. We need to constantly look ahead at a wide range of emerging treatments and techniques and take a view on the scientific, legal, ethical and institutional developments. We are aware that scientific advances and social changes can have significant implications for the current and predicted institutional set-up of medical and scientific regulation in the UK. It is therefore necessary for us to be able to assess which changes are likely to happen within relevant time-frames.

15. The Authority will consult with national and international experts in order to identify the new treatments and techniques that are a priority for more detailed assessment. These priorities will be addressed through our annual business planning process. This new approach to horizon scanning will be launched at the international ESHRE conference in June in Berlin. We are also currently reviewing the rules which govern the use of donor gametes and the provisions for assessing the welfare of the child.

16. We will publish the outcome of the horizon scanning and planning process, and the resulting policy reviews will be included for the first time in the Authority's

2005/6 business plan. The insights generated through this year's horizon scanning will also inform our input into the Department of Health's review of the 1990 Act. Better horizon scanning can also enable us to involve stakeholders at an earlier stage in our thinking.

In recent years the HFEA has given greater priority to public consultation and accountability. We use a range of different approaches to take account of changing and often conflicting public views. For example:

- We consulted widely on our Corporate Plan (2004/9) which gave us very clear pointers for priorities for the next 5 years. We also consulted stakeholders on the current (6th) edition of the Code of Practice.
- The HFEA now holds some of its meetings in public, with the opportunity for observers and Authority members to meet after the formal meeting.
- We are recruiting a patient advisory panel to give us greater insight into the patient's perspective.
- The sex selection consultation included different strands of research, including a MORI poll and focus groups, and was launched in Parliament. It led to more than 700 written responses.
- The HFEA is this year reviewing 3 of its major policy areas – evidence of our awareness that empirical evidence and public opinion are never static: gamete and embryo donation, child welfare assessment (Section 13 (5) of the HFE Act) and HLA/PGD. For our HLA/PGD review, in addition to gathering latest scientific and clinical information, we have commissioned research that aims to find out *how* people reach their opinions, how they negotiate them with other opinions and to establish non-negotiable 'bottom lines' for different stakeholders.

”Composition, expertise and approach of the HFE Authority, its code of practice, licensing arrangements and the provision of information to patients, the professions and the public”

17. The HFEA is not only a regulator, but also has an important role to play in policy advice and communication. It is the only UK regulator currently engaged in licensing research and not only clinical activities. Its other unique main function is the development and maintenance of a reliable and fully functioning register of important patient, treatment and offspring information. We believe that the regulatory model created by the HFE Act has overall met the needs, and still has the confidence, of clinics, patients and the public. It is often seen as an example of successful regulation inside and outside the UK.⁴

⁴ See for example: Better Regulation Task Force *Scientific Research - Innovation with Controls*, January 2003: “The HFEA was [...] the first statutory body of its kind in the world, and over the years has gained recognition worldwide as a leading authority on infertility regulation.”

18. We are making considerable efforts to modernise and strengthen our approach to regulation, inspection and the recording of patient information and can envisage changes in the Act that would be beneficial in this respect. Significantly, we are planning to restructure our inspection process by developing a targeted, risk-based approach which focuses on those clinics and practices where harm is most likely to occur. To this end we have developed a risk matrix which we now need to pilot and evaluate.

Our improved clinical governance and risk management also includes:

- Targets to improve our regulation of clinics. These concern response times for licence applications (3 months for treatment, 4 months for research applications), the conduct and planning of inspections and the follow-up of inspection reports.
- A dedicated website for all licensed clinics, outlining our procedures, spelling out our targets and keeping licence holders informed of our activities. We are also investigating ways of making our Code of Practice a more accessible and up-to-date document in order to make compliance easier.
- The ground-breaking alert system as part of an overall safety agenda, which also includes a programme of unannounced inspections.
- Training and expanding our inspection team, including nurse and counselling inspectors. We have also piloted gathering patient feedback during inspections, which we will roll out in the whole inspection programme.
- Considerable investment in and major work on our registry function, with data accuracy and security recognised as of utmost importance. Our new system includes double data entry, validation, historical and ongoing audit. Storing and providing reliable data on treatments and outcomes will become even more important in light of the abolition of donor anonymity.
- A new clinics database. Together with the improved register it can now be used far more effectively to streamline inspection processes (focussing on identified cases and practices that represent an increased risk) and policy making. In addition, we will now use a far broader range and depth of data to provide more meaningful information for the new edition of our patient guide.
- Concerted and innovative work with other professional bodies on how new technologies can be used to increase patient safety (bar-coding, chip technology etc).
- Implementation of the '5 Principles of Good Regulation' developed by the Better Regulation Task Force.

19. Regulating research is one of the most important functions of the HFEA. Research involving early embryos plays a crucial role in improving clinical practice and outcomes in reproductive medicine. But embryo research remains one of the most controversial practices of modern science. Setting up the HFEA and its research regulation role was a response to this controversy and requires high standards of transparency and accountability. We have re-organised the regulatory team in order to build on and expand our research expertise, including a new 'Head of Research' post and a new Research Officer. We have also created a specialised Research Licensing Committee in order to fulfil our ambitious targets for deciding research licence applications. Our first annual Research Conference was held in 2003 and we are consulting the research community about the level of licence fees and the streamlining of the research application process.

20. Apart from licensing embryo research, the HFEA has no explicit role as a research institution. But we are aware that many of the safety or wider social questions surrounding the use of new reproductive technologies can only be answered through better research. The move from research into clinical practice also needs to be effectively monitored and regulated. A better way of achieving this may be to introduce into the 1990 Act a new category of licence that covers clinical trials in licensed clinics. We are also liaising closely with other research organisations, like the National Perinatal Epidemiology Unit and the MRC to encourage more work on the safety and outcome of reproductive technologies.

21. Another important issue is the question of follow-up studies. Our register contains much information that, if effectively linked with other research data bases, could help answer many important research questions about the long-term outcomes of assisted conception technology. This would, however, require the relaxation of section 33 HFE Act (confidentiality). Currently, where we identify research needs we try to encourage such research to be conducted and funded.

22. The 1990 legislation and the early years of the Authority were characterised by a strong emphasis on confidentiality and at times even secrecy. The use of assisted conception techniques and for example donor gametes is now viewed in a different light and a more open and communicative approach is now actively promoted, for example by the Department of Health. We are very conscious that the confidentiality of patient data remains of utmost importance, but we feel that the confidentiality requirements of the HFE Act should be brought in line with the wider context of sharing and protecting data in health and research institutions.

We are keen to communicate our policy and practice more effectively than in the past.

- We have re-launched a more accessible and informative public web-site.
- Following extensive consultation with users of fertility services, we are rewriting and significantly extending our range of patient information leaflets.
- We have redesigned and re-launched our patient guide, together with Dr Foster.
- We now provide regular parliamentary briefings, and are working closely with the All Party Group on Infertility and other interested Parliamentarians in order to keep members of both Houses involved in our work.
- We are now signed up to the 'Plain English Campaign' and are planning to submit all our new information material to user-reviewing in order to achieve the 'Crystal Mark'.

23. The composition of the Authority is a matter for the Department of Health. Inevitably, within a specialised field there can be concerns about conflicts of interest. We have addressed this by using an extended range of independent peer reviewers. We have also started to co-opt external experts onto the Authority subcommittees and working groups in order to extend our basis of expertise. This includes experts from outside the UK and Europe. We will continue to monitor whether the composition of the Authority enables us to fulfil our statutory duties.

A forward look

24. The HFE Act and the regulatory model it embodies can be said to have stood the test of time well. But a review of the Act is now welcome for a number of reasons⁵, some of which we have outlined in this document (the definition of the embryo, confidentiality and the register), but also concerning issues like artificial gametes and developments in family law (the new Adoption and Civil Partnership Acts).

25. Over the last few years, the HFEA has undergone significant change. We are confident that we are now better equipped to deal with the ongoing and new challenges of reproductive technologies. We have strengthened our regulatory capacity, we have improved our register function, and we have opened up various channels of two-way communication with the public, patients and our stakeholders. We believe that our ability to bring all these areas together is a particular strength of the HFEA and helps to make us a more effective and publicly accountable regulator.

⁵ We are happy to share with the Committee our detailed thinking to date on areas where we would like to see the HFE Act 1990 amended.

26. The HFE Act and the creation of the HFEA represent a careful settlement of social and ethical disagreements that are and will remain controversial. Such a settlement must be subject to periodic review to ensure that it continues to have the confidence of Parliament, patients and the wider public. This inquiry and the proposed review by the Department of Health provide such an opportunity.