House of Commons Select Committee – Human Reproductive Technologies and the Human Fertilisation and Embryology Act (1990)

Response to Call for Evidence from the British Fertility Society

1. British Fertility Society

The British Fertility Society is a multidisciplinary professional non profit organisation whose membership is approximately 800 and whose membership includes clinicians, counsellors, nurses, embryologists, andrologists and research scientists; working in the field of infertility and assisted reproduction. Our core objective is to increase knowledge and understanding in this field.

2. Overview of HFE Act (1990)

We believe that the HFE Act (1990) has provided an important and useful regulatory framework for the development and practice of assisted reproduction technologies in the United Kingdom. Since 1990 the expansion of treatment options to the infertile and the introduction of new techniques has been enabled. Research in this field has also been permitted, albeit with constraints additional to those currently imposed on other areas of medical research. Nevertheless there is scope for improvement.

Interpretation and implementation of the primary legislation has seen an unnecessary burgeoning of the bureaucratic burden placed on providers and an unreasonable shift of emphasis from the clinical and scientific aspects of assisted reproduction to the social aspects in the inspection and licensing process. Whilst we recognise the importance of counselling in the context of assisted reproduction its role and use must be kept in perspective.

Standards of clinical and scientific practice should be established by the relevant professional organisations and should not be part of the regulatory framework. The role of the regulatory process is in their monitoring and the application of effective sanctions. However, if qualitative aspects of clinical and laboratory services are to be assessed, the parameters and end points must be objective and agreed with the relevant professional organisations.

It is important that a review of the legislation recognises the broadly permissive approach which has existed so far and has been important in the development of the field and that the review does not introduce further restrictions and bureaucracy.

3. Context of provision of services

Four main points of context are relevant in the review:

a. The European Directive

This will undoubtedly have a major impact on the way standards are achieved in IVF laboratories. A new way of accreditation of laboratories

is likely to be implemented that will necessitate changes to the current inspection and licensing process.

b. The maturity of the IVF process

When the HFE Act was conceived IVF was in its relative infancy. Now it is commonplace treatment with broadly standardised scientific and clinical methodology. In the UK it is estimated that 1% of all children born are conceived in this way and in some other Western countries this figure is higher. A review of the act must take account of this evolution and the relative commonality of assisted reproduction while continuing to safeguard public health concerns.

c. National Institute of Clinical Excellence Guidelines

The full implementation of the NICE Guidelines is likely to shift the balance of assisted reproduction provision from the private sector to the NHS. Governance, audit and confidentiality processes already exist in the NHS sector to a robust standard. The governance of mainstream assisted reproduction must fall within these existing processes. In this context the role of the "person responsible", unique in the health care setting, should be replaced by the more conventional model of lead clinician, clinical director or lead scientist. Accountability for compliance with the regulatory requirements must fall to the Chief Executive (in the NHS model or similar functionality in the private sector) as it does with all other aspects of health care.

d. Risk Management

The major areas of risk in assisted reproduction exist in the clinical and laboratory setting. The structure of the Authority and the emphasis in the regulatory process must reflect this and not the softer issues.

4. Main Areas of Concern

a. Regulation and policing

Outcome measures of regulation are not clearly defined and there is no evidence that this has produced compliance with the code of practice and improved clinical practice. One body, the Human Fertilisation and Embryology Authority, develops policy and structures in regulation as well as providing the "policing" of that policy. We believe that these functions and accountability for them need to be separated. This review, together with approaching accreditation in line with the European Directive provides that opportunity.

b. Confidentiality and consent to disclosure

It is now time to bring the confidentiality provisions in line with those that are already in existence within the health care setting. The current provisions on confidentiality have stifled communication and research. The possible exception to this is treatment with donor gametes.

c. Welfare of the child

The current provisions for the assessment of the welfare of the child require revision in the context of the widespread nature of infertility and its management. The process is overly bureaucratic and places additional and, in the vast majority of cases, unnecessary burdens on primary care. We recognise the importance of the welfare of the child but the act must allow for more flexibility in its assessment. The regulations should recognise the contribution of provider expertise in this respect.

d. Anonymity

The loss of anonymity for donors remains an area of concern with regard to its impact on donor recruitment. A review should allow for reconsideration of a twin track approach.

e. Methodology of inspection and licensing

As has been stated the application of the regulations as applied through the licensing and inspection process is an overly bureaucratic, top heavy and time consuming process which despite this does not address the key areas of medical concern. A review of the legislation must take account of the well established nature of many clinical assisted reproduction services, bringing accountability for their governance within existing mechanisms in the health service, limiting the inspection role to trouble spots, application for new licences and reducing the frequency of renewal of licence inspections. If the HFEA are to monitor the "qualitative" aspects of the service, these will require to be clearly defined and objective end points established through discussion with the relevant professional organisations.

The establishment of the European Directive will require new quality assurance systems to be put in place by providers. The accreditation resulting from this must contribute to ***but not add to*** the current licensing regimen.

f. Funding

The burden of funding of the regulatory process falls to those that are being regulated (the providers) and those that are the subjects of the regulation (the patients). Patients and public are not made aware of this burden. The cost far exceeds any similar levy that is applied by other quangos on a per capita basis and, in its scope, has no parallel in the health care setting. With the major shift to the NHS setting likely with the implementation of the NICE guideline, it is time to fund the HFEA adequately from exchequer resources and remove this iniquitous and anomylous burden from the provider and patient.

g. Outlying treatments

Gamete intra fallopian transfer (GIFT) is a technique which is infrequently practised but involves the manipulation of gametes and has the potential for many of the risks and consequences of IVF (particularly multiple pregnancy). The act must include within its remit this therapy. Intra uterine insemination with ovarian stimulation is in a similar situation, its main risk being multiple pregnancy. This practice should also be considered within a review of the legislation.

26th May 2004

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