# Parliamentary Brief

## Human Fertilisation and Embryology Bill

Second reading, House of Commons

### Introduction

The BMA supports the provisions in the Human Fertilisation and Embryology Bill, which relate to assisted reproduction treatment and the use of human embryos for research purposes. The BMA also supports the current model of UK-wide regulation with the broad framework set out in legislation and a statutory body - the Human Fertilisation and Embryology Authority (HFEA) - interpreting and applying the framework. This provides the flexibility that is needed in such a fast-moving area. Regulation in this area continues to be appropriate because:

- Statutory regulation provides important protection for those seeking treatment, much of which is on a self-funded basis within a commercial setting.
- To maintain public confidence, it is important that there are clear controls to prevent clinics and research institutions crossing the boundary of what, as a society, we consider to be acceptable practice. The existence of a statutory regulatory body can provide protection for clinics and help to promote an environment within which carefully monitored research and innovation can flourish.

The existing legislation in this area has worked well over the past two decades. It has, however, been overtaken by scientific and medical developments and changes in societal attitudes. This means that although the approach of the legislation – a broad statutory framework with an independent authority to license clinics and laboratories and produce guidance for them – is still the right one, the specific provisions in the Act have become outdated.

This briefing considers three issues – on which there will be free votes in the House of Commons – which are of particular concern to the BMA. They are embryonic stem cell research, embryo testing and access to licensed treatment (usually referred to as welfare of the child).

### Embryonic stem cell research

Research using human embryos has been taking place since the 1970s, when Patrick Steptoe and Robert Edwards were first exploring the possibility of treating infertility through in vitro fertilisation (IVF). Although a voluntary licensing system was in place in the UK from the mid 1980s, embryo research first became subject to statutory regulation in 1991. Since then, any scientists wishing to use or create human embryos in a laboratory for research purposes cannot do so without first obtaining a licence from the HFEA and being subject to inspections. **The BMA supports this safeguard.**

A number of conditions apply to any research using or creating human embryos, most significant of which are that the embryos used or created in research must not be kept beyond 14 days after fertilisation, nor should they be transferred to a woman. Failure to comply with these conditions is a criminal offence.

For a licence to be granted, researchers must demonstrate that the use of embryos is necessary: if animal studies, for instance, could achieve the same result, the use of human embryos is not

permitted. A licence will only be granted if the proposed research fits within the permitted research purposes in the Act. The original research purposes were:

- To promote advances in the treatment of infertility,
- To increase knowledge about the causes of congenital disease,
- To increase knowledge about causes of miscarriages,
- To develop more effective techniques of contraception, or
- To develop methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation.

Three further purposes were added by Parliament in 2001:

- Increasing knowledge about the development of embryos,
- Increasing knowledge about serious disease, or
- Enabling any such knowledge to be applied in developing treatments for serious disease.

These further purposes enabled UK researchers to benefit from breakthroughs in embryonic stem cell research which took place in the USA in 1998. This opened up the possibility, not envisaged in 1990, that embryo research could be used to better understand – and potentially to develop therapies for – a wide range of common diseases. Such research involves culturing embryos in the laboratory until about five days after fertilisation.

**The BMA strongly supports the use of human embryos in research, subject to the statutory controls described above.** IVF itself would not have been developed without the embryo research conducted in the 1970s and 80s. Further embryo research led to improvements in IVF success rates and the development of new techniques for the treatment of infertility. Embryo research has also enhanced our understanding of genetic disease and led to the development, by UK researchers in the early 1990s, of a way of testing very early embryos for particular diseases. Through this technique, known as preimplantation genetic diagnosis (PGD), thousands of healthy babies have been born to families at high risk of having affected children. Finally, embryonic stem cell research, whilst still in its early stages, is already advancing our understanding of early human development and the processes involved in particular diseases such as Parkinson's and motor neurone disease. In future, it could lead to the development of new, cell-based therapies for these conditions.

*Research using human admixed embryos*

Clause 4 lists the types of embryos containing both human and animal material which can be created for research purposes. Conditions apply to their use including that the embryos must not be kept beyond 14 days nor can they be transferred to a woman.

One area of research, for which UK scientists were recently granted a licence, is a form of embryonic stem cell research which uses animal, instead of human, eggs. Animal eggs are used solely to avoid the use of human eggs, which are in very short supply and are prioritised for treatment. The resulting embryos, which have only a tiny proportion of animal DNA in them, can be used to derive stem cells which can act as a model for diseases like motor neurone disease in the laboratory.

**The BMA believes that the use of human embryos in research should be subject to the same strict controls, regardless of whether they are purely human or contain some animal DNA**. We therefore support the provisions in the Bill and look forward to the results of the newly-licensed research projects.

**Embryo testing**

The Bill lays out the circumstances in which embryos can be tested in the laboratory before they can be transferred to the woman:

- *Preimplantation genetic screening*: sometimes known as aneuploidy screening, this technique is of benefit to women at high risk of a failed IVF cycle or an early miscarriage. It screens for chromosomal abnormalities, enabling these women to increase their chance of establishing and maintaining a pregnancy.
- *Preimplantation genetic diagnosis*: this enables couples who know they are at significant risk of having a child with a particular genetic condition to avoid the transfer of embryos affected by the condition.
- *Preimplantation sex selection for medical reasons*: this enables couples who know they are at significant risk of having a child with a genetic condition affecting one sex to avoid the transfer of embryos of that sex.
- *Preimplantation tissue typing*: sometimes referred to as 'saviour sibling' treatment, this use of embryo testing allows the selection of an embryo which is a tissue match with a sibling suffering from a life-threatening or serious medical condition.
- *Preimplantation parental testing*: this is to determine, in cases where a laboratory mistake may have been made, whose sperm and egg have been used to create a particular embryo.

Because the testing of embryos was in its infancy when the Human Fertilisation and Embryology Act was debated in Parliament in 1989/90, provision for this procedure is very limited in the current legislation. **The BMA is pleased to see the framework expanded as this will give clarity to the HFEA and to centres offering embryo testing.**

*Preimplantation genetic diagnosis*

Schedule 3(3) 1ZA(1)(b): Preimplantation genetic diagnosis (PGD) can be requested by couples who are at high risk of having a child with a particular genetic disease, such as cystic fibrosis or Duchenne muscular dystrophy. **The BMA supports the use of embryo testing for this purpose and agrees that PGD should only be available in cases where there is significant risk of a serious disease.** We are also pleased that the wording of this clause is broad enough to include serious conditions which are not necessarily present at birth (late onset conditions such as Huntingdon's disease) and those where there is a high chance, though not a certainty, that the condition will appear (non-fully penetrant conditions such as familial breast or colon cancer).

*Preimplantation tissue typing*

Schedule 3(3) 1ZA(1)(d): **The BMA supports the use of preimplantation tissue typing in all cases where this is the best option for treatment of a sibling whose condition is life threatening or serious**. A key concern about such cases has been the possibility of psychological harm resulting to the child who would be selected and born to be a donor. Although likely to be as loved as any other child, concerns have been expressed that the child might resent being "selected", feel less wanted or less respected as an individual. The BMA believes that these hypothetical risks of harm needed to be balanced against other harms, primarily the real harm to the sibling who would suffer or die without this treatment.

*Sex selection and preferences for affected embryos*

Schedule 3(3) 1ZB(1): The BMA supports the prohibition on sex selection for social reasons. The BMA's view is that the use of technology and the selection of embryos should primarily be for the purpose of reducing suffering and impairment. We therefore welcome inclusion of clauses 14(4)(9) and (10), which prohibit selection of embryos in order to increase the chance of having a child with a serious disability, illness or medical condition – for example, where parents wish to have a child with the same disability as them.

**Welfare of the child**

**The BMA supports the retention of the requirement to consider the welfare of the child to be born before treatment is offered.** We believe that where a health professional is involved in assisting conception, that person has some responsibility to ensure that a future child is not subjected to foreseeable serious harm. This means that there should be a presumption to provide treatment, but that access should be denied where the practitioner concludes, based on good evidence, that any child born to a particular individual or couple would to likely to suffer serious harm.

Clause 14(2)(b): The BMA supported the original drafting of the Bill which sought to remove from the welfare of the child provision the term "the child's need for a father". We have consistently rejected the idea of applying inflexible rules on access to fertility treatment, believing instead that each application should be considered on its merits. Assessments should be made on the individual factors in each case rather than on blanket restrictions applied to certain categories of people or family arrangements. Whilst there is evidence that children raised by single women are more likely to be disadvantaged, this is not the case for children born to single women or lesbian couples who choose to start a family on their own by assisted conception. Early research shows that these children fare just as well as those born by assisted conception to two heterosexual parents.

The removal of the term "the child's need for a father" from the legislation prompted significant debate in the House of Lords, with the Government ultimately tabling a compromise amendment which inserted "the child's need for supportive parenting" into the clause instead. The BMA is disappointed at this compromise. Whilst supportive parenting is clearly a good thing, such a phrase seems to move away from the 'foreseeable risk of serious harm' approach and is open to differing interpretations in practice. This may mean that prospective patients are subjected to more intrusive questioning about their lives than they are at present.

**Parenthood**

Clauses 33 to 47: **The BMA supports the widening of the definition of "parents" under the Bill,** in particular that women (whether a civil partner or a cohabiting partner) can register as a second parent. We believe that it is in the interests of the child to have a formal legal relationship with both parents who will be responsible for their care and upbringing.

**Gamete donation: openness and donor anonymity**

The BMA would like to see increased openness between parents and their donor-conceived children. **We support the Government amendments made to the Bill in the House of Lords which strengthen the requirement for clinics to provide information to patients about the importance of telling their children that they were donor conceived**.

The BMA is concerned, however, that the lack of donor anonymity may make such openness less likely. We opposed the removal of donor anonymity which Parliament approved in 2004. We are concerned that parents who are unwilling for their child to contact the donor when they reach 18 may be less likely to tell their child they were donor conceived. The BMA is disappointed that the Government has not taken this opportunity to review the policy.


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