

Ethics, legal, social, counselling

The moral status of the embryo: the human embryo in the UK Human Fertilisation and Embryology (Research Purposes) Regulation 2001 debate



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Abstract

The use of the embryo in research into birth defects, infertility and the possible therapeutic value of embryonic stem cells, has given rise to vigorous discussion of the ethical, moral and legal status of the embryo. This paper considers the parliamentary debate that surrounded the passing of legislation in the UK in 2000 governing the use of the embryo in research. Underlying disagreement by members of Parliament as to whether embryo research was permissible, were considerable differences regarding when life was thought to begin – whether at the moment of fertilization of the egg, or whether after 14 days, at the time of the beginnings of cell differentiation, and the point after which the embryo can no longer split to form twins. Those who favoured the latter view argued that, while the conceptus might possess a unique genetic formula, it had only the potential for life before 14 days, the development of human life being a gradual and continuous process. They considered it mistaken to accord the embryo full human rights. Those who adopted an opposed standpoint insisted that life was present and actual from the moment of conception and therefore sacrosanct and inviolable. The notion of the pre-embryo, they maintained, merely serves to disguise the embryo's humanity.

Keywords: cloning, embryo, ethics, HFEA, human

Introduction

The ethical, moral and legal status of the human embryo has attracted much interest while provoking passionate debate on both sides. Lockwood defines the moral status of the embryo by delineating the concept of personhood, that it is the cluster of capacities which distinguish us from non-human animals, and then argues that mere potentiality for personhood does not in itself confer upon an embryo a serious right to life. Furthermore, Lockwood asserts that what is required in addition is the presence of brain life, which almost certainly does not develop until the second trimester. In the US, the administration attempts to bring the unborn under the umbrella of federal health protections, extending certain health benefits

to fetuses. The new move does not, however, mandate that embryos used in research are given the same protection as fetuses, children and adults (Weiss, 2002). Currently in the US, embryos are regarded as the ball of cells that constitute the earliest stages of human development. Fetuses represent a later stage of development and already have a limited amount of protection under federal research rules. Scientists, however, are increasingly turning their attention towards embryos to improve understanding of birth defects and infertility, and as a source of embryonic stem cells that researchers hope to turn into therapies for a variety of degenerative diseases. While the wider public engages in debate, there is greater concern about the meaning of the word 'embryo', especially when used interchangeably with the term fetus. According to US experts,

these changes are worrisome and seen as an attempt to give embryos new legal rights and possibly the status of a person under the US law.

In the UK, the complex status of fetus and embryos has been intensely debated under different guises of law, morality and ethics, often with little conceptual depth. Further complications are added with the array of laws and approaches in existence: UK, European approaches, the European Convention on Medicine, Human Fertilisation and Embryology Act (HFEA) (1990) and now the Human Rights Act (Bahadur, 2001). The central question has always been: when does life begin, and when does life acquire the status of a 'person' with its own rights? It might be easier to explore the fetal status first. In English law, a fetus does not have any rights of its own. It is felt that the human being does not exist as a legal person until after birth, and it follows that it cannot be seriously argued that an embryo is a legal person. The embryo, however, is widely given a measure of respect, although this is not absolute. The legal status of the non-classical embryo created using nuclear substitution and where no fertilization had occurred, as in the creation of 'Dolly the sheep', presents a major new development that needs to be taken into account in our understanding of the meaning of an embryo. Such an 'embryo' is not explicitly defined in the HFEA Act (1990) (Bahadur, 2001; Bahadur and Nielsen, 2001; Nielsen *et al.*, 2001). The most recent House of Lords ruling appears to carve a politically favourable definition for a CNR embryo and side-steps the scientific meaning of sperm-egg fertilization (HFEA website/media, 2003). The weight of decision was based on the 'intention of Parliament' when the HFEA Act (1990) was enacted. Despite the ban on reproductive cloning, the acceptance of this embryo as being no different from the fertilized embryo may inadvertently have led us down the slippery slope to the acceptance of cloning given the preliminary information on success of human cloning (Edwards, 2003; Zavos, 2003). Advances in reconstructed gametes, and embryos created therein, may shed newer perspectives on our perception of an embryo (Lacham-Kaplan, 2001; Tesarik, 2002; Eichenlaub-Ritter, 2003). A spectrum of patients recorded their views on the status of the human embryo (McMahon *et al.*, 2003) and the moral status of nuclear replacement embryos (CNR) appears to be gaining lesser status than embryos derived from fertilization (Hansen, 2002). A recent ESHRE paper, entitled 'The moral status of the pre-implantation embryo', provided qualitative information by discussing practical aspects of embryo use in research, diagnosis and freezing, and offers definitions of the various stages of the embryo prior to implantation (Shenfield *et al.*, 2001). The significance of the 14-day limit was forecast in relation to what is meant when cloned, non-fertilized embryos are concerned (Bahadur and Nielsen, 2001; Nielsen *et al.*, 2001), and which factor gained special significance in the Parliamentary debate. There is breaking news that European members of parliament (MPs) voted against scientists to carry out research on stem cells taken from embryos and which could see this type of research being outlawed across the European Union (www.bbc.co.uk).

Background to the Human Fertilisation and Embryology (Research Purposes) Regulation (2001) debate

Any research project in the UK involving the creation, keeping or using embryos outside the human body must be licensed by the HFEA. To grant a research licence, the HFEA must be satisfied that the research is 'necessary or desirable' and that the use of human embryos is essential. The HFEA may grant licences for research projects only in the following five specific categories [HFEA Act 1990, Schedule 2, paragraph 3(2)]:

- (i) Promoting advances in the treatment of infertility;
- (ii) Increasing knowledge about the causes of congenital disease;
- (iii) Increasing knowledge about the causes of miscarriage;
- (iv) Developing more effective techniques of contraception; or
- (v) Developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation.

Against the backdrop of scientific advances and interest in therapeutic cloning and embryonic stem cells (de Wert and Mummery, 2003), and following the Human Fertilisation and Embryology (Research Purposes) Regulation (2000) debate, the UK Parliament in January 2001 chose to approve new regulations [Human Fertilisation and Embryology (Research Purposes) Regulations 2001]. This allowed the purposes for which human embryo research may be permitted to be extended to increasing knowledge about serious disease and for developing treatments for such disease, and specifically three categories were added:

- (vi) Increasing knowledge about the development of embryos;
- (vii) Increasing knowledge about serious disease; and
- (viii) Enabling any such knowledge to be applied in developing treatments for serious disease.

Human embryos obtained with appropriate consent for a research project may not be used for any other purpose. The following activities involving human embryos are not permitted under UK legislation:

- Keeping or using an embryo after the appearance of the primitive streak or after 14 days, whichever is earlier;
- Placing a human embryo in an animal;
- Placing the nucleus of a cell of an embryo with a nucleus taken from a cell of another person, another embryo, or a subsequent development of an embryo;
- Altering the genetic structure of any cell while it forms part of an embryo; and
- Using embryos for any other purpose except in pursuance of a licence.

The HFEA policy would not license embryo splitting with the intention of increasing the number of embryos for transfer. Significantly, the three added categories (vi–viii) are likely to cover the fast moving area of embryonic stem cell research.

The Human Reproductive Cloning Act (2001) banned reproductive cloning by making it an offence to place in a woman a human embryo which has been created otherwise than by fertilization.

The debate

With a view to extending the categories of research under the Human Fertilisation and Embryology Act (1990), the parliamentary debate under the heading 'The Human Fertilisation and Embryology (Research Purposes) Regulation (2000)' (www.parliament.gov.uk) took place (references which follow relate to appropriate columns and sections of the debate appearing in *Hansard*). There was much discussion of the moral, ethical and legal issues concerning the human embryo along with confusion surrounding its definition. Significantly, the concept of the 14-day embryo attracted much interest. This paper will consider this notion, as well as the ways in which the Members of Parliament viewed the embryo.

MPs agreed on the principle that individual human life should be accorded respect, but vigorously debated the question of when, precisely, life could be defined as coming in to being. Those in favour of embryo research argued that the moment of the penetration of the egg by the spermatozoon did not represent the beginning of a human life. They contended that, up to the first 14 days, the embryo remains a cluster of undifferentiated cells, some of which go on to form not the fetus but the placenta and membranes (Audrey Wise, column 92; *all subsequent numerical references are to column numbers*). It is only with the development of the 'primitive streak' at 14 days that an individual life could be defined as commencing; before this point, the nervous system has not developed (Mr Wigley, 76). Many fertilized eggs perish in the course of nature before implantation (Kenneth Clarke, 39): it seems that nature has no great respect for the preimplantation embryo. Prior to implantation, the embryo has only the potential for life: it may split to form twins, and individuality cannot therefore be said to have established itself before this point (Mr Wigley, 76). Mr Key quoted the Archbishop of York's opinion on this matter: 'Genetic union is decisive in that it produces a unique genetic formula, but does not at that stage produce a unique and identifiable organism... If the morally significant dividing line occurs when there is a physical entity in which unique moral value can be perceived, this transition [i.e. the point at which twins emerge] would seem to mark that change, though this is not to imply that the developing conceptus before differentiation lacks all moral status.' (102)

The 14-day period was therefore seen as a landmark relating to the emergence of a single individual by some MPs (John Hannam, 116). Others argued that, for legal purposes, conception could be defined as beginning at the moment of uterine implantation, rather than the fertilization of the egg, at about the sixth or seventh day; as the legislation sought to stop all embryo research after conception, it was important to define when this occurred (Sir David Price, 74). This opened up the possibility of permitting research only before this earlier stage.

A recurring theme in the debate was the view that human evolution is a gradual process, and it would be inappropriate to

accord the same human rights that apply to an adult to the pre-embryo. Rosie Barnes quoted the Archbishop of York again to articulate this view: individual lives, he stated, 'begin with chemistry and they reach their fulfilment in mystery. There is no doubt about the depth, wonder, moral worth and religious significance of personhood, but the transitions on the way to it are not clean, clear and decisive... Biologically speaking we are looking at a continuous process. The philosophical mistake in the belief that full and instantaneous human rights are somehow created at the moment of conception lies in the surreptitious assumption that in those very early stages of embryonic life there is some real personal entity to which our moral language can apply.' (80) While in favour of embryo research, Rosie Barnes, acknowledged that this argument could support an opposing position – if the development of personhood is a gradual process, it is arbitrary to set a date up to which research would be allowed. David Wilshire cited a similar argument to the Archbishop of York's in order unambiguously to justify embryo research: 'we all start as human material and develop into a human person' (70).

Embryo research was also justified by comparing the current legal status of the fetus under the regulations governing contraception. Mr Key pointed out that the moral issues raised by embryo experimentation were the same as those involved in the issue of intrauterine contraceptive devices and forms of oral contraception that involve the loss of pre-implantation embryos: we do not regard this as unethical or illegal (103). In a similar argument, Rosie Barnes quoted Joyce Poole's *The Cross of Unknowing*, which reminds us that the fetus is not accorded the same rights as a baby: in cases of miscarriage, the fetus is not baptized (83).

MPs devoted some of their attention to considering the merits or otherwise of embryo research – what were its achievements hitherto and whether they justified continuing the practice – in an attempt to balance a sense of the consequent benefits and losses. Nevertheless, the key question remained that of whether the embryo, in the first 14 days of its existence, could be defined as a living human being. Mr Key pointed out that this was an important ethical and moral argument, and not a scientific one, as science does not provide the right framework for addressing issues of value (103). Indeed, MPs were on surer ground when they debated the ethical dimension of the question, rather than attempting to base their arguments on scientific definitions.

Those opposed to research on embryos approached the question from a religious standpoint that considers the individual life as sacrosanct. John Bowis quoted John Marshall, professor of clinical neurology at the University of London, who states this principle: 'because the entity has the potential to become a person, one affirms that it should not be interfered with, that nothing should be done that prevents it realising that potential' (117). If an embryo can perish, Bowis contends, then surely it had life to begin with (116). The view is based on the premise, stated by Sir Bernard Braine, that the embryo prior to 14 days is not a cluster of cells but a human life: that the living human has its origin in the meeting of the spermatozoon and the egg, at which point an irreversible process of development begins, and human life becomes actual rather than possible (48). Sir David Price quotes the Warnock report to support this view: 'At fertilization the egg and sperm

unite to become a single cell. The nucleus of this cell contains the chromosomes derived from both parents. This single cell is totipotent, as from its develop all the different types of tissues and organs that make up the human body, as well as tissues that become the placenta and fetal membranes during intra-uterine development' (73). Nevertheless, the report concluded that the respect given to the embryo cannot be absolute and must be weighed against the benefits of research.

Given this assumption, several MPs suggested that the term 'pre-embryo' was used merely to disguise the embryo's humanity – if it were not human, experimenters would not be interested in working on it (Alan Amos, 105; Mr Duffy, 55; Sir Bernard Braine, 53). Michael Alison contributed to this argument by suggesting that, even at 14 days, the embryo is still almost invisible and imperceptible, yet we agree that a life has emerged, and it is inviolable and sacrosanct (66). He goes on to infer that a life was there from the beginning, but is only in evidence, only identifiable, from day 14 (67). He suggests that, if there is any doubt as to the human status of the fertilized ovum, it must be given the benefit of the doubt (67; Sir Bernard Braine, 53).

Opposition to embryo research was largely based on the ethical principle that a life cannot be sacrificed for the benefit of another, or many others (Michael Alison, 66). The end does not justify the means; the knowledge does not justify the destruction of a human life (Kenneth Clarke, 40). Alan Amos asserted that embryo research infringes the moral rule that we should not use others for our own needs (107). In support of his argument, he quoted from the Helsinki Declaration, the World Medical Association's statement of medical ethics: 'In research on man, the interests of science and society should never take precedence over considerations relating to the well-being of a subject' (104). He also cited the Geneva Convention code of medical ethics, 1949, which asserts the traditional principle of medical ethics, 'I will maintain the utmost respect for human life from the time of conception' (104).

Amos objected to research on embryos as amounting essentially to a means, not of treating embryos affected by genetic disorders, but effectively of culling them (104). Certain MPs argued that this was a human rights issue that violated the right to life of the disabled and denigrated their status. Mr Duffy, for instance, stated that it is arbitrary to decide who should be allowed to be born and who should not, and that a disabled child has no right to live (58). There was much debate concerning the special joys and pain associated with giving birth to a child affected by a genetic disorder, and whether it was therefore right to allow diagnostic techniques that would result in the destruction of affected embryos. Somewhat emotively, those opposed to the idea of embryo research invoked the spectre of human experimentation in Nazi Germany to illustrate the dangers of a belief that the end justifies the means and the individual is dispensable (Sir Bernard Braine, 54; Sir Michael McNair-Wilson, 91). They also raised the fear of a slippery slope: if research were to be permitted up to 14 days, then why not, sooner or later, 16 days, or 17 days, or longer? (Mr Duffy, 57).

Conclusion

The 14-day embryo therefore acquired a significance in the debate that it did not have for the Warnock Commission, in being seen by some as defining the point at which human life became actual rather than potential. Those opposed to embryo research, however, tended to take the position that life was present from the moment of fertilization of the egg by the spermatozoon.

I believe the MPs had a difficult task in deciding on this delicate, sensitive and somewhat emotive subject, whilst taking account of their constituents' views. While respecting the diverse views their decision will help researchers towards understanding the development of embryos and of serious disease under the umbrella of a regulatory body. I feel vindicated by the significance of the 14-day embryo, which we had forecast in an earlier edition of *Reproductive BioMedicine Online* (Bahadur and Nielsen, 2001). Its importance and interest is likely to heighten with greater focus on CNR embryos and embryos created from reconstructed gametes and haploidization. Future scholars may most likely draw moral and ethical distinction between the non-fertilized and fertilized embryos, causing in turn pressure on legislation to revisit this area. This is something we have already previously pointed out, and independent evidence of this is referenced. The latest ban on embryonic stem cells from European MPs seems a setback for European researchers who wish to unlock the potential promise embryonic stem cells may hold. While I can find reasons to support embryonic stem cell research under controlled and regulatory condition, my concern is the limits of its beneficial reach to human suffering given the commercial interest which is likely to drive this field. The unavailability of AIDS drugs to the poor African nations is just one example of this tension between scientific progress and commerce, given that much of the groundwork for research is supported by public monies. Finally, the House of Lords decision to legally assign the CNR embryo the same entity as the fertilized embryo as explicitly defined in the HFEA Act (1990) defies logic, given that the Act reinforces its intent to mean the entity created by the fertilization of the spermatozoon and egg. Whilst the decision-making process appears like 'a riddle wrapped in a mystery inside an enigma', a phrase used by Winston Churchill, it inadvertently accepts 'reproductive cloning', by logical extension. The decision also seemingly leads to a complex series of tension and contradictions within the triangle of Human Rights Act (1998) (Bahadur, 2001); Human Reproductive Cloning Act (2001) and the Human Fertilisation and Embryology Act (1990).

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