

This is the text of my introduction to *Human Embryo Culture: Discussions concerning the statutory time limit for maintaining human embryos in the light of some recent scientific development* (2017) Nuffield Council on Bioethics. The typeset version and the full report can be downloaded at

## Introduction

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Through the Human Fertilisation and Embryology Act 1990, lawful human embryo research was restricted to specific conditions in the UK. Prior to the enactment of the legislation, there was no legal prohibition on such research, and the only regulation was voluntary. In 1990, local research ethics committees were not yet universally established; they were not formally mandated by NHS administrative norms, let alone a legal requirement.<sup>i</sup> The context in which the statutory limit on embryo research was debated was thus not one in which no research was happening, but one in which there was no legally binding regulation.<sup>ii</sup>

When the legislation came before them, parliamentarians were offered a choice between prohibiting all embryo research and permitting it in defined circumstances and for a limited range of prescribed purposes. They chose the latter course and legislated that embryos could not be kept or used ‘after the appearance of the primitive streak’. This is a potentially ambiguous biological term, but it has been given more precise legal definition by the gloss that ‘the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day on which the process of creating the embryo began, not counting any time during which the embryo is stored’.<sup>iii</sup> Strictly, therefore, the rule should be described as the ‘primitive streak rule’ not the ‘14-day rule’. This possible significance of this distinction between biological and chronological divisions is discussed below.

Although initially controversial, this statutory limit has been maintained for over 25 years.<sup>iv</sup> During this time, there was no scientific prospect of sustaining embryos *in vitro* beyond the permitted period. That changed in 2016 with the publication of two papers

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in *Nature*.<sup>v</sup> Some have asked whether this meant that the question of the limitations on embryo research should be revisited. The Nuffield Council on Bioethics decided to convene a workshop with group of experts from a range of fields and disciplines to explore whether there was a case for a more detailed piece of work on the issue.

This report contains the background paper that was commissioned to provide a context for the discussion along with a note of the discussions from the day. The discussions were held under the Chatham House Rule so that themes and issues are recorded but not attributed to individuals in order to facilitate the most candid exchange of views possible. Participants, including those who were invited but were unable to attend the meeting, were given the opportunity to provide short comments in order to ensure that a broad range of perspectives was adequately represented. These observations are also set out later in this document. We hope that these materials will provide a resource for those, who are considering whether there is a case for revisiting the limits on embryo research. For the present, the Council does not aim to reach any conclusion on the merits of the issue, which would require much more detailed work, but to draw out the questions that would need to be addressed by those who advocate a review.

#### *Jurisdictional functions of the rule*

It is perhaps helpful to remind ourselves of the jurisdictional functions of the 14-day rule. These serve to explain those roles that are played by a rule of this sort, which are independent of the point at which the rule is fixed. It is likely that any proposal to revisit the rule will need to take these functions into account.

First, the rule limits the jurisdiction of the licensing authority to authorise research involving human embryos. This is a regulatory tool, and is not necessarily a mechanism for directly translating a moral judgment on the status of the embryo. Fourteen days is not the point at which special respect is conferred by the law. That is accorded to all human embryos, which are protected by the prohibition of unlicensed storage and use.<sup>vi</sup> Behind this prohibition lie the creation of a dedicated ethics committee and the specification of limitations on the purposes for which research may be permitted. However, the structure of the regulatory system is essentially similar to that for the use of non-embryonic human tissue, and so is not necessarily connected with personhood issues and the particular status issues around the human embryo. It is also similar to the regulatory structure for oversight of animal research. Each of those creates a prohibition of activities, with powers in a licensing authority to permit them within certain limits and subject to oversight. The 14-day rule sits within a regulatory framework that accords some respect to all human embryos at whatever stage of development. The specific questions raised by the rule are, therefore, not concerned with whether respect should be accorded to the human embryo but with what respect requires when it comes to be balanced against other competing, publicly valued, interests.

The relationship between this aspect of the rule and the moral status of the embryo is therefore indirect. It plays a function *within* a wider regulatory system and it is necessary to consider that system as a whole in order to assess whether due regard has been paid to the moral significance of the embryo. The 14-day rule serves to distinguish those cases where the law has determined that the moral value of the embryo will *always* preclude the pursuit of knowledge through research from those in which a 'balancing exercise' needs to be separately undertaken into each research proposal.<sup>vii</sup> Under the current framework, human embryo research cannot be lawful in pursuit of the recognised objectives after 14 days, no matter how important the results might be. However, in the period before this, the Human Fertilisation and Embryology Authority (HFEA) is empowered to license projects provided that the statutory purposes that Parliament laid down are being pursued. In effect, it distinguishes ethical questions that are to be regarded as closed from those which are to be treated as open to further reflection.

The second of the jurisdictional functions that is served by the 14-day rule is to reserve the decision to amend (or not) the rule to Parliament. In most areas of reproductive ethics, the HFEA was given supervisory stewardship responsibility.<sup>viii</sup> However, its opportunities to determine the ethics of embryo research have been severely curtailed by the Act. This applies to the grounds on which such research can be justified<sup>ix</sup> as well the time- or development-based limit.<sup>x</sup> Parliament has reserved its sovereignty over these aspects of embryo research and any change would need to be justified in terms that would persuade it to legislate differently. The next section considers some implications of this for the structure of an argument for reform.

There is also little or no scope for the courts to have a say in the point of embryo development at which the line between 'acceptable' and 'unacceptable' research is drawn. In principle, the need to classify new entities, such as the recently generated 'synthetic human entities with embryo-like features' (SHEEFs), might be seen as an opportunity for judges to drive policy.<sup>xi</sup> However, litigation over how cloning should be classified suggests a recognition that the intention of Parliament to create a comprehensive regulatory framework will lead to judges construing new techniques in a way that incorporates them into the special regulatory framework rather than developing a judicially defined legal status.<sup>xii</sup> Provision is already made for Parliament to make regulations to bring within the definition of embryo entities that contain human DNA but would not otherwise be included.<sup>xiii</sup> Arguments based on current definitions, common law and human rights law, are therefore not material to the question with which we are concerned here.

The 14-day rule played a third jurisdictional function during the Parliamentary debates on embryo research in 1990. This was to maintain a focus on the question that the Government wanted to be considered, that is, research on very early embryonic development. Without such a limit, the debate could properly have encompassed a range of developmental stages from a small number of undifferentiated embryonic

cells to a fully formed fetus with a reasonable chance surviving outside the womb.

The recommendations in the 'Warnock Report' of 1984, which foreshadowed the 1990 legislation, were concerned with 'the very earliest stages of human embryonic development' and were crafted in order to limit permissible research to this period.<sup>xiv</sup> The Report was fully aware of the possibility of scientific development and the demand that might lead some to seek research at a later stage. It identified a number of potential future developments, including use of human embryos to test drugs and ectogenesis ('creating a child entirely *in vitro*').<sup>xv</sup> The former becomes a particular issue of interest with the advent of SHEEFs.<sup>xvi</sup> It noted that some argued that the latter 'would make it possible to study in detail normal and abnormal human development at the embryonic and foetal stages'.<sup>xvii</sup> The Report addresses this issue by saying the following:

"We appreciate why the possibility of such a technique arouses so much anxiety. There are however two points to make about this. First, such developments are well into the future, certainly beyond the time horizon within which this Inquiry feels it can predict. Secondly, our recommendation is that the growing of a human embryo *in vitro* beyond fourteen days should be a criminal offence."<sup>xviii</sup>

Thus, the 14-day rule served the jurisdictional purpose of limiting the discussion of human embryo research in a way that ensured that some concerns, such as those about sentient beings becoming non-consensual research subjects, could be excluded from the scope of debate. This did not stop them being raised by some parliamentarians in debate, but it enabled Ministers to respond reasonably by saying the strict limits provided reassurance that such developments were not under consideration in the vote before them. It is probable that any re-opening of the 14-day rule would need to find an equivalent jurisdictional device to delineate the debate.

This continuing need for a clearly defined line is independent of the question of how a proposed limit might be justified. As the discussion of the origins of the current rule set out in this report show, there may be a variety of justifications offered for a limit and, if the decision is for Parliament, it is not necessary for there to be agreement on these justifications. Lawmakers may have independent, and even incompatible, reasons for supporting a particular limit provided that a consensus is reached on the desirability of the outcome. However, it is unlikely that a different line would be acceptable to legislators if it were considered 'arbitrary' in the sense of being random and without any reasoned basis.<sup>xix</sup>

The justification of a jurisdictional division to play the equivalent function of the 14-day rule need not necessarily be found in biological development, although much of the discussion explores such possibilities. The legislation explicitly links this time limit with the emergence of the primitive streak, but there has never been a consensus on why this is morally significant. The Warnock Committee explained it in terms of the

beginning of individuation.<sup>xx</sup> In Parliamentary debates, this was elaborated as indicating the final point at which twinning might occur.<sup>xxi</sup> The Warnock Committee considered a range of other points at which a line might be drawn. It noted that for utilitarians, there might be significance in the beginnings of a central nervous system (at around 22–23 days) or functional activity that would show that pain could be felt (not known in 1984), with the precautionary assumption that the legal limit should be fixed a few days earlier in order that there would be no possibility of pain.<sup>xxii</sup> Some have taken this as a supplementary justification for the 14-day rule. This is not explicit in the original Warnock Report, although there is a reference to the view of the Royal College of Obstetricians and Gynaecologists that a 17-day limit might be appropriate, corresponding to the point at which early neural development begins.<sup>xxiii</sup> These are developmental markers. However, there was also some discussion of the relevance of implantation, which will never be an actual stage for an embryo *in vitro*.<sup>xxiv</sup>

Discussions at the Council's workshop also hinted at a different type of argument, based on the availability of other sources of information. This approach would suggest a limit that was fixed to ensure that embryos were not used in research when the relevant data could be gathered in other ways. As explained later in this Report, knowledge of early human development is based on the Carnegie Collection of human embryos.<sup>xxv</sup> Where this is incomplete, early human development is a 'black box' into which we cannot see.<sup>xxvi</sup> This knowledge base can be supplemented and refined in a number of different ways. The current legal framework enables research up to the end of day 14. From around 28 days, scientists can glean information from examining embryos that have been lost in miscarried pregnancies. We might see this an 'obscured window' into human embryo development. A veil of ignorance lies over the period between 15 and 28 days.<sup>xxvii</sup> The time limit on embryo research thus might be fixed not by reference to a developmental stage but by the availability of other sources of information.

### *The structure of the case for embryo research*

Building on these reflections on the origins and functions of the 14-day rule, it is possible to draw out from the debates over human embryo research in the period that led up to the Human Fertilisation and Embryology Act 1990 the structure of any future case for revisiting it. The parliamentary decision constituted a collective conclusion that the prospects for public benefit from embryo research could sometimes outweigh the restraining presumption against it. If legislators were persuaded that this might sometimes be the case, then decisions on individual research projects could properly be delegated to the HFEA. Parliament has already revisited this question in relation to the component of the law relating to embryo research that concerns the permitted purposes, and been persuaded that the prospect of useful scientific knowledge is sufficiently important to justify extending the permitted purposes.<sup>xxviii</sup>

The first limb of any case for changing the 14-day rule would therefore need to be a

compelling case that significant scientific gains can reasonably be expected from an extension of the period in which research was permitted. Without such a case, there is no reason to reopen the rule. This case could be based on arguments that we have good reason to think that an extension in the time permitted for research would bring knowledge within our grasp that would enable us to address issues of public importance. It would also be appropriate to show that only extended embryo research can be expected to deliver those benefits.

Those who are concerned about the possibility that the 14-day question should be revisited point to a number of weaknesses in the scientific case. The benefits of extending research further have not been clearly articulated. Critics of existing embryo research raise concerns that it has not delivered the benefits that it promised and counsel about being taken in by hype. They also point out that, until very recently, researchers have only been able to sustain embryos *in vitro* for about seven days. It may be premature to be thinking about extending the rule until we know more about the period between days seven and 14. The interest in doing so now looks to many critics like a classic example of a 'slippery slope', where regulatory measures that were claimed to curtail a scientific free-for-all are removed as soon as they begin to operate in that fashion.<sup>xxix</sup> But it is not necessary to be a critic of embryo research to conclude that public confidence in its governance depends on the 14-day rule operating as a real constraint and, if there is to be change, then the scientific case will need to be compelling.<sup>xxx</sup>

The second limb of such a case would be the identification of a new regulatory constraint that could play the jurisdictional roles identified in the previous section. That is: it needs to be clear enough to provide a workable definition of the powers of the HFEA for the purpose of legal accountability; it needs to be narrow enough to ensure that Parliament retains oversight; finally, it needs to be robust enough to give Parliamentarians confidence that they are not committing themselves to a broader acceptance of research than they are being invited to consider.

### *Untimely arguments*

The explanation of the role of the 14-day rule that was outlined above suggests that some of the arguments about human embryo research that could be made should be disregarded for the purposes of a narrow reconsideration of the rule. These can crudely be summarised as those that argue for two positions that would make the rule superfluous. For those who believe that no research involving human embryos is ever permissible and also to those who believe that no special respect is owed to such embryos, the 14-day rule is merely a tactical device that secured a truce in a deeper clash of values. Our workshop did not seek to engage with that wider debate, although it is noted by a number of contributors.<sup>xxxi</sup> It is, of course, difficult to exclude the fundamental question of the status of the human embryo from discussion but our brief was to concentrate on the ways in which it becomes intertwined with arguments

addressed more specifically to the 14-day rule itself and any possible replacement. This report is intended to make a contribution to understanding the role and rationale of the rule. If it were decided to revisit the regulation of embryo research, these two positions would need to be given full consideration. It is not necessarily the case that the 14-day rule, or an alternative playing a similar set of jurisdictional roles, would ultimately be considered appropriate if the issue of embryo research were revisited.

A second set of arguments that were outside the scope of this piece of work but that would be relevant to a full reconsideration concern the relationship of the 14-day question to other social currents. We have already noted concerns about 'slippery slope' arguments that are held in some quarters. It is likely that any discussion of the embryo research rules would be affected by public confidence in the integrity of scientists. The experience of recent Parliamentary interventions, such as the developments in the regulation of mitochondrial replacement therapies, would also be relevant. It is likely, also, that connections would be made between the embryo research debate and discussions about the law on abortion.

For these reasons, and no doubt for others besides, this brief review of the issues is much more narrowly focused than would be required if we were hoping to reach a conclusion on whether it was appropriate to extend the circumstances in which embryo research could be licensed. Nor has our discussion aimed to move towards any recommendation about the form any replacement for the 14-day rule might take. Rather, we have aimed to scope the issues that would need to be examined so that an informed view can be taken on whether this is the correct time to consider a change in the law.

### *Reflections*

In the light of these considerations, the contributions here recognise the scientific value of the recent advances in sustaining embryos (not just human embryos) *in vitro* for longer periods of time. This offers exciting prospects for learning more about embryo development. Our current knowledge of embryo development is much less secure than many might imagine. In general terms, there is reason to think that understanding early embryo development better is likely to shed light on the causes of miscarriage. This is a major cause of distress and unhappiness. However, the workshop did not identify particular reasons for thinking that rapid progress could be made with research into embryos for extended periods. It seems unlikely that Parliament would entertain a change in the law without having a much more clearly articulated scientific case to consider.

The workshop did not set out to establish whether there was a preferred candidate for a new limit for research that could satisfactorily replace the existing one. However, we anticipated that some plausible options would emerge in the discussion. A number of biological markers were identified and there was also some discussion of incremental

progression based on time alone. Some possible adaptations to the way in which the rule functioned were raised. It might, for example, be possible to consider extending permissible embryo culture for some or all of the period between 15 and 28 days but only in order to permit observational studies, with interventional research being proscribed during this period. It might be possible to restrict the range of legitimate purposes for any extended period more narrowly than those that currently apply up to the end of day 14. It might also be possible to improve the regulation of embryo research by introducing a principle of economy, equivalent to the ‘refine, reduce and replace’ (3Rs) objective in relation to animal research.<sup>xxxii</sup> These are all valuable observations. There was no consensus as to which approach would be most ethically satisfactory, nor which would be most likely to secure the public acceptance that is widely thought to be the key to the durability of the current 14-day rule.

Insofar as there are conclusions to be drawn from this workshop, it would seem that there is not at this stage a clear case for change of the sort that would persuade legislators of the need for action, either in relation to the prospect of scientific benefit or in relation to the availability of a satisfactory alternative regulatory tool. The regulation of human embryo research remains an important and interesting bioethical question but it is not clear why the question of the 14-day rule should be regarded as a priority for those charged with developing public policy in the area at present.

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## Notes

<sup>i</sup> Circular HSG(91)5 required the creation of committees by February 1992 in accordance with the guidance in Department of Health (1990) *Local research ethics committees* (London: Department of Health).

<sup>ii</sup> Warnock M (2004) *Nature and mortality: recollections of a philosopher in public life* (London: Continuum), at page 123; Department of Health & Social Security (1984) *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (London: Department of Health & Social Security), (‘Warnock Report’), at paragraphs 11.16-7. (The Committee was chaired by the English philosopher Dame Mary (now Baroness) Warnock.)

<sup>iii</sup> Legislation.gov.uk (2017) *Human Fertilisation and Embryology Act 1990*, available at: <http://www.legislation.gov.uk/ukpga/1990/37/contents> (as amended by the Human Fertilisation and Embryology Act 2008), section 3(4). The original (1991) text was phrased slightly differently: “beginning with the day when the gametes are mixed...” See also: section 4A(3).

<sup>iv</sup> Session Two of the Workshop considered why this might have been so and how it should be interpreted.

<sup>v</sup> Deglincerti A, Croft GF, Pietila LN *et al.* (2016) Self-organization of the *in vitro* attached human embryo *Nature* **533(7602)**: 251-5; and Shahbazi MN, Jedrusik A, Vuoristo S *et al.* (2016) Self-organization of the human embryo in the absence of maternal tissues *Nature Cell Biology* **18(6)**: 700-8.

<sup>vi</sup> Legislation.gov.uk (2017) *Human Fertilisation and Embryology Act 1990*, available at: <http://www.legislation.gov.uk/ukpga/1990/37/contents>, at Section 3.

<sup>vii</sup> A further jurisdictional distinction between research and reproductive uses of embryos is discussed in the background paper, see especially paragraph 43ff.

<sup>viii</sup> On this point more generally, see my early discussion of the regulatory structure created by the Act in Montgomery J (1991) Rights, Restraints and Pragmatism, 54 *Modern Law Review* 524-34.

<sup>ix</sup> Legislation.gov.uk (2017) *Human Fertilisation and Embryology Act 1990*, available at: <http://www.legislation.gov.uk/ukpga/1990/37/contents>, Schedule 2 para 3A.

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- x            ibid, section 3(4).
- xi           Synthetic human entities with embryo-like features have been produced in the laboratory using stem cells from somatic tissues; see: Aach J, Lunshof J, Iyer E and Church GM (2017) Addressing the ethical issues raised by synthetic human entities with embryo-like features *eLife* 6: e20674.
- xii          *R. v. Secretary of State for Health ex p. Quintavalle (on behalf of Pro-Life Alliance)* [2003] UKHL 13.
- xiii         Section 1(6) of Legislation.gov.uk (2017) *Human Fertilisation and Embryology Act 1990*, available at: <http://www.legislation.gov.uk/ukpga/1990/37/contents>.
- xiv         Department of Health & Social Security (1984) *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (London: Department of Health & Social Security), at paragraph 11.1.
- xv          ibid, at chapter 12.
- xvi         See n.13 (above).
- xvii        Department of Health & Social Security (1984) *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (London: Department of Health & Social Security), at paragraph 12.7.
- xviii       ibid, at paragraph 12.8.
- xix         The issue of 'arbitrariness' is explored further in the background paper, esp. paras 37, 47-8, in Session One of the workshop report and in the contribution from Dave Archard.
- xx         Department of Health & Social Security (1984) *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (London: Department of Health & Social Security), at paragraph 11.22.
- xxi         Kenneth Clarke MP, *Hansard HC deb.*, 23 April 1990 (col.31).
- xxii        Department of Health & Social Security (1984) *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (London: Department of Health & Social Security), at paragraph 11.20.
- xxiii       ibid, at paragraph 11.21.
- xxiv        ibid, at paragraph 11.21.
- xxv         See especially the background paper paragraphs 7-8, and Julian Hitchcock's contribution.
- xxvi        The Guardian (5 June 2016) *Inside the 'black box' of human development*, available at: <https://www.theguardian.com/science/2016/jun/05/human-development-ivf-embryos-14-day-legal-limit-extend-inside-black-box>.
- xxvii       See Sheny Chen and Andrew Chisholm's contribution for discussion of what is thought to occur in this period.
- xxviii      Legislation.gov.uk (2017) *The Human Fertilisation and Embryology (Research Purposes) Regulations 2001*, available at: <http://www.legislation.gov.uk/uksi/2001/188/contents/made>.
- xxix        See the contribution from David Jones, although he does not use the language and examines the corrosion of public reason and weakening of regulation as different elements of the problem.
- xxx         See the contributions from Katrien Devolder and Dave Archard.
- xxxi        See especially those from David Jones and Shaun Pattinson.
- xxxii       See the contribution from David Jones for this point.