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DONATION OF 'SPARE' FRESH OR FROZEN EMBRYOS TO RESEARCH: WHO DECIDES THAT AN EMBRYO IS 'SPARE' AND HOW CAN WE ENHANCE THE QUALITY AND PROTECT THE VALIDITY OF CONSENT?

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ABSTRACT

This paper analyses elements of the legal process of consent to the donation of 'spare' embryos to research, including stem-cell research, and makes a recommendation intended to enhance the quality of that process, including on occasion by guarding against the invalidity of such consent. This is important in its own right and also so as to maximise the reproductive treatment options of couples engaged in *in vitro* fertilisation (IVF) treatment and to avoid possible harms to them. In Part 1, with reference to qualitative data from three UK IVF clinics, we explore the often delicate and contingent nature of what comes to be, for legal

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purposes, a 'spare' embryo. The way in which an embryo becomes 'spare', with its implications for the process of consent to donation to research, is not addressed in the relevant reports relating to or codes of practice governing the donation of embryos to research, which assume an unproblematic notion of the 'spare' embryo. Significantly, our analysis demonstrates that there is an important and previously unrecognised first stage in the donation of a 'spare' embryo to research, namely: consent to an embryo being 'spare' and so, at the same time, to its disuse in treatment. This is not explicitly covered by the Human Fertilisation and Embryology (HFE) Act 1990, as amended by the HFE Act 2008. Having identified this important initial stage in the process of consent to the donation of a 'spare' embryo to research in conclusion to Part 1, in Part 2 we analyse the idea of consent to an embryo's disuse in treatment on the basis that it is 'spare' with reference to the legal elements of consent, namely information as to nature and purpose, capacity, and voluntariness. We argue that there are in fact three related consent processes in play, of which the principal one concerns consent to an embryo's disuse in treatment. If the quality of this first consent is compromised, in turn this will impact on the quality of the consent to the donation of that 'spare' embryo to research, followed by the quality of consent to future cycles of assisted reproduction treatment in the event that these are needed as a result of a donation decision. The analysis overall is of central relevance to the debate as to whether, and if so when, it should be permissible to request the donation of *fresh* embryos for research, as opposed to those that have been frozen and, for instance, have reached the end of their statutory storage term. This has a particular bearing on the donation of embryos to stem-cell research since there is a debate as to whether fresh embryos are most useful for this.

Keywords: Donation of fresh or frozen embryos to research, including stem-cell research; Quality and validity of consent for donation of embryos to research; Ethical and legal issues in donation of fresh or frozen embryos to research

INTRODUCTION

Embryo research, including stem-cell research, may use 'spare' embryos that pass from the assisted reproduction clinic to the research laboratory. The donation of such embryos to research requires the consent of the donating couple.[1] On its face, the question of when an embryo

[1] The relevant provisions of the Human Fertilisation and Embryology (HFE) Act 1990, as amended by the HFE Act 2008, are discussed in Part I, S.I, and III, and further in Part 2.

is 'spare' appears relatively simple: for example, an embryo that is not needed because a couple has decided not to pursue further treatment, or one that is deemed 'unsuitable for treatment', for instance according to embryology criteria. However, the idea that an embryo is 'unsuitable for treatment' and therefore 'spare' is not as straightforward as it may at first appear. Rather, this conclusion may be surprisingly delicate and, in some circumstances, contingent. Analysis of the decision-making process that an embryo is 'spare' in fact raises a number of significant questions about the extent of the information about and control regarding any given embryo that a couple may and should have, and so about the quality of their consent to the donation of any given embryo to research.

The purpose of our work is to analyse elements of the legal process of consent to the donation of 'spare' embryos to research and, in the light of this, to make a recommendation designed to enhance the quality of that process, including on occasion by guarding against the invalidity of such consent. This is important in its own right and also to maximise the reproductive treatment options of couples engaged in *in vitro* fertilisation (IVF) and to avoid possible harms to them. Our work is of central relevance to the debate as to whether, and if so when, it should be permissible to request the donation of *fresh* embryos for research, as opposed to those that have been frozen and, for instance, have reached the end of their statutory storage term.[2] This has a particular bearing on the donation of embryos to stem-cell research since there is a debate as to whether fresh embryos are most useful for this.[3] Given the widely practised nature of assisted reproduction treatment and the increased scope of domestic embryo research,[4] coupled with the development of stem-cell research here and overseas, the issues we address are of considerable national as well as international significance.

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[2] This is now 10 years in the UK under the HFE Act 1990 (as amended), ibid, s 14(4).

[3] For conflicting views on this, see eg D Hoffman and others, 'Cryopreserved Embryos in the United States and their Availability for Research' (2003) 79 Fertil Steril 1063–9, indicating that fresh embryos are better for stem-cell research. For a contrary view, see A Sjögren and others, (2004) 9 Reprod Biomed Online 326–9 which directly compares fresh and frozen embryos. In this study, 'the efficiency by which frozen-thawed embryos gave rise to new hES cell lines was 3.7 times better than with fresh surplus embryos'. The authors continue: 'These findings suggest that frozen-thawed embryos are superior to fresh surplus human embryos in hES cell establishment, which also avoids specific ethical problems associated with embryo donation in a fresh IVF cycle.' (At 326.)

[4] Permissible research purposes now transcend those relevant to reproduction *per se*, and include:'. . . (a) increasing knowledge about serious disease or other serious medical conditions, (b) developing treatments for serious disease or other serious medical conditions, (c) increasing knowledge about the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a).' HFE Act 1990 (as amended), above n 1, Sched 2, para 3A(2).

We address our purpose in two stages: in Part 1, we consider how a decision is made that an embryo is 'spare', with attention to the relationship between professional and patient input into this, highlighting the often delicate and contingent nature of what comes to be, for legal purposes, a 'spare' embryo. The way in which an embryo becomes 'spare', with its implications for the process of consent to donation to research, is not in fact addressed in the relevant reports[5] relating to or codes of practice governing the donation of embryos to research, which assume an unproblematic notion of the 'spare' embryo. Indeed, although the HFEA *Code of Practice* stresses 'that only fresh or frozen ... embryos *not required for treatment* can be used for research', it makes no mention of the important decision-making process that results in an embryo being labelled 'spare'.[6] The issue has also received almost no academic, and within that no legal, attention.[7] Significantly, our analysis in Part 1 demonstrates that there is an important and previously unrecognised first stage in the donation of a 'spare' embryo to research, namely: *consent to an embryo being 'spare' and so, at the same time, to its disuse in treatment*. Since this stage is not explicitly covered by the Human Fertilisation and Embryology (HFE) Act 1990, as amended by the HFE Act 2008, its legal analysis requires some interpretation of the HFE Act and surrounding law.

Having identified this important first stage in conclusion to our analysis in Part 1, in Part 2 we analyse the process of consent to donation, with reference also to the common law relating to consent, showing that there are in fact three interrelated consent processes at stake: consent to an embryo being 'spare' and so to its disuse in treatment; consent to the donation of that embryo to research; and consent to further fresh cycles of assisted reproduction treatment in the event that these are necessary as a result of a prior donation decision. In the light of our analysis, we make a recommendation aimed at enhancing the legal quality of these consents and the protection of reproductive futures.

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[5] Department of Health, *Stem Cell Research: Medical Progress with Responsibility*, (Department of Health, London 2000) <http://www.doh.gov.uk/cegc>. House of Lords Select Committee on Stem Cell Research, *Stem Cell Research: Report from the Select Committee* (The Stationary Office, London 2002) 25.

[6] HFEA, *Code of Practice* (8th edn, 2009, updated 2011), in force October 2011, para 22.7(h), our emphasis. The same wording was used in the 7th edition (2007) para G.5.13.1(b); the 6th edition (2003) used the phrase 'surplus to treatment' (para 5.8(ii)). The MRC Steering Committee, *Code of Practice for the Use of Human Stem Cell Lines* (Version 5, April 2010) likewise makes no reference to this aspect of the donation decision.

[7] An exception from the perspective of ethics is S Holm, 'The Spare Embryo – A Red Herring in the Embryo Experimentation Debate' (1993) 1 Health Care Analysis 63–6. R Morgan's 'Embryonic Stem Cells and Consent: Incoherence and Inconsistency in the UK Regulatory Model' (2007) 15 Med Law Rev 279–319 is concerned with other important issues.

Our discussion in both parts makes use of our qualitative research at three UK clinics which provide IVF and which are also involved, directly or indirectly, in the provision of embryos for stem-cell research.[8] We interviewed 44 health professionals and scientists and also conducted six ethics discussion groups (EDGs).[9] The value of these groups, which consisted of three to six participants, lay in the opportunity for those involved to explore ethical issues that arose in the interviews in some depth and as a member of a group of colleagues, guided by a philosopher. Taken together, the interviews and the EDGs provide a unique insight into what in practice may affect the determination of an embryo as 'spare', with implications for the process of consent to donation that are explored particularly in Part 2. Our data were collected between 2007 and 2009. Certain practices may have changed, but ethical and legal issues remain about past, present, and future practice, particularly the ongoing question of the circumstances in which fresh, rather than frozen, embryos may be sought for donation to research.

PART 1: WHO DECIDES THAT AN EMBRYO IS 'SPARE'?

I. INTRODUCTION

In this Section I, we first note the statutory provisions on consent to the use or donation of embryos. In Section II, we analyse how an embryo comes to be 'spare' with reference to clinics' freezing policies. Lastly, in Section III, we start to interpret the law as it applies to the relationship between freezing policies and patient choice.

The statutory provisions on consent are contained in Schedule 3 of the amended HFE Act 1990, compliance with which is a condition of a clinic's licence under section 12(1) of the Act.[10] A couple must consent in writing to the use of their embryos (and gametes) in their treatment, or to their donation to research (or for use in training or in the treatment of others, which do not concern us here).[11] Either the man or the woman can withdraw consent (for any of the above purposes, or to continued storage) before an embryo's use.[12] For the purposes of donation to research, the HFEA *Code* stipulates that '[e]mbryos will be regarded as having been

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[8] Above as detailed in the 'asterisk' note. For further details of this aspect of our research, see K Ehrich, C Williams, and B Farsides, 'Fresh or Frozen? Classifying 'Spare' Embryos for Donation to Human Embryonic Stem Cell Research' (2010) 71 (12-6) Soc Sci Med 2204–11.

[9] The interviews were conducted by Kathryn Ehrich and the EDGs by Bobbie Farsides.

[10] See also HFEA, above, n 6, Licence conditions T57, R18.

[11] HFE Act 1990 (as amended), above, n 1, Sched 3 paras 1(1) and 2(1).

[12] Ibid, Sched 3, para 4(1)(2).

used . . . as soon as they are under the control of the researchers . . . and are being cultured for use in research'.[13] As indicated above, we consider questions about the legal position regarding the degree of control that a couple may have over their embryos that arise as a result of our analysis in the final stage of this Part 1 (Section III), as a prelude to our further analysis of the law in Part 2.

II. HOW AN EMBRYO COMES TO BE 'SPARE'

In this section, we discuss some of the factors that affect the determination of an embryo as 'unsuitable for treatment', some of which are intrinsic and some contingent. The crucial factor on which we focus here is the *freezing policy* of the clinic at which a couple is being treated. Research Manager 27 (Site 2) described the issue of freezing as 'probably the thing that most affects whether couples are getting material through to . . . research', adding, 'I think that the differences between those policies in the different places have quite radical effects.' First, we give some short background about embryo potential and freezing policies in general.

A. The Live-birth Potential of Each Embryo: Grading Issues

In debates about the moral status of the embryo, it is typically assumed that all embryos *in vitro* have the potential to produce a live-born child. In fact, this is not the case, since embryos vary enormously in their potential to continue developing *in vitro* prior to, and *in vivo* after, transfer. For simplicity, we will refer to this fact as 'embryo quality'. For this reason, embryos are initially assessed by embryologists in the first few days after fertilisation (usually on day two and/or three) and graded according to various (currently morphological) criteria, including the number of cells they possess on any given day post-fertilisation and the degree, if any, of fragmentation. As Embryologist 5 (Site 1) observed: 'I mean obviously an embryo is a being, you know, it's a mixing of the genetic material, it's, you know, it is the start of something but that doesn't necessarily mean it is going to continue.' Embryologists monitor embryos daily with the aim of being able to select the best for transfer to the uterus on day three or later. Whether embryos are transferred later than day three will depend on whether the clinic has the facility to culture the embryos to blastocyst stage, reached on day five or six following fertilisation (which is becoming more common), and whether there are enough embryos to justify trying to take them on to this stage so as to make the best possible selection between them. Clinician 37 (Site 1) referred to this selection process as 'uncover[ing]

[13] HFEA, above, n 6, 'Interpretation of Mandatory Requirements', Box 22B.

embryo potential as much as possible'. The imprecise nature of the relationship between embryo quality and pregnancy potential means that there will inevitably be some variation in the way embryos are graded by different embryologists. That said, clinics try to overcome this by standardising their assessments as much as possible, although the presence of some subjectivity in some cases appears inevitable with the current criteria.[14] As Embryologist 26 (Site 2) observes: 'It's . . . always going to be an art in choosing to some extent.'

In short, despite the presence of a number of embryos as a result of superovulation, not all embryos from a treatment cycle will have the potential to produce a live-born child. However, provided sufficient eggs are retrieved and fertilised, there is likely to be more than one with this potential. In the first place, this raises the question of how many to transfer to a woman's uterus.

B. Transfer of Fresh Embryos

The question of how many embryos to transfer is an ethical issue in its own right. This is because of the significant possibility of a multiple-gestation pregnancy developing, with risks of greater complications for the mother and/or fetuses during the pregnancy, with possible long-term consequences in the born children, such as some degree of disability as the result of prematurity.[15] In 2003, the HFEA recommended that in women under forty, a maximum of two embryos should be transferred, and a maximum of three in women over this age.[16] The issue received renewed attention in 2006 when the risks of multiple-gestation pregnancies were addressed by an expert group convened to report to the HFEA, which recommended that only one embryo should be transferred at a time in suitable cases, known as 'single embryo transfer' (SET).[17] Accordingly, following a consultation process, the HFEA has further revised the guidance in its *Code*.[18]

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[14] A related question here is whether there should be a national grading process for embryos. There is an attempt to do this by the Association of Clinical Embryologists and there is a published grading system for blastocysts.

[15] See eg HFEA, Expert Group on Multiple Births after IVF, *One Child at a Time: Reducing Multiple Births after IVF* (October 2006). Current figures are that more than 25% of IVF pregnancies in the UK are still multiple, that is, 40% of all IVF births are twins or triplets. See <http://www.oneatatime.org.uk>.

[16] See HFEA, The Scientific and Clinical Advances Group, 'Embryo Transfer Review', SCAG(04/03)01, <http://www.hfea.gov.uk/docs/SCAG_Embryo_Transfer_April03.pdf>.

[17] HFEA Expert Group, above, n 15, Executive Summary, 8–9.

[18] HFEA, above, n 6, T123: 'The centre must not exceed the maximum multiple birth rate specified by Directions.' And see 'Interpretation of Mandatory Requirements', Box 7A, and paras 7.1, 7.2.

The number of embryos that remain after transfer will depend on the number that were produced in any given treatment cycle. Since the quality of each embryo is variable (and more will be known about embryo quality if it has been possible to culture them to blastocyst stage), the question will then arise as to whether the remainder, from either a day three or day five/six transfer, can be frozen for possible subsequent use. This takes us to the issue of the freezing policy of any given clinic and whether, in the event that embryos are not frozen for subsequent clinical use, the remaining fresh embryos might be sought for research, including stem-cell research.

C. Unpacking Clinics' Freezing Policies

1. Numbers and Quality

Some clinics may have (or have had) a policy requiring a *minimum number* of embryos, for instance three, before freezing a couple's additional embryos is recommended to them. There may be several elements to this. First, as Embryologist 5 (Site 3) noted, less than 70% of day 3 cleavage stage (non-blastocyst) embryos survive thawing, although the survival rate typically increases to near 90% if blastocysts (day five or six) have been frozen. The rationale is that out of three thawed embryos, there might be two suitable to transfer. Connected with this is a concern about not raising false hopes in patients by preparing a woman for a frozen embryo transfer and then finding that there is only one or even none to transfer. In fact, the move towards SET and increased use of blastocyst culture will impact on this issue, since a cycle in which only one embryo is transferred in women under thirty-five will become the norm, though subject to exceptions.

A second aspect of freezing policies concerns embryo *quality*. The thought here, from a clinical perspective, is that it is not worthwhile freezing poor-quality embryos and that this might give false hope to a couple. However, an important issue is at what stage the final assessment of embryo quality is made. If this is done at day three, for instance because the clinic does not have the facility to culture embryos to blastocyst stage or because there were not deemed enough embryos to justify doing this, it may sometimes be the case that if those embryos had been allowed to develop further, some of them may in fact have proved to have good live-birth potential. The occasional unpredictability of embryo development was noted by various participants in our study. An important question in relation to embryo quality will be whether a couple is informed of this possibility so that, if they wish, they can choose to give one or more of those embryos (not those that are patently non-viable) the *chance* of a pregnancy by having them frozen even if, on the balance of probability, the assessment as to poor quality is more

likely than not. Clinician 37 (Site 1), a clinic with the facility for blastocyst culture, talked of 'giv[ing] the embryos the benefit of the doubt … Some of them against the odds, they continue to develop to a blastocyst and we offer patients [the choice] to freeze them'.

Since there is a concern about the number of embryos that may survive thawing, the financial cost of freezing and subsequent transfer of thawed embryos needs to be considered. Some freezing policies are derived from a 'value for money' perspective. If a couple would have to pay for the freezing and then the intended replacement cycle (which may well total over £1000), they would need to make a financial judgment—taking into account also the clinic's success at frozen replacement cycles, and the estimated quality of the embryos and their likelihood of surviving the freeze and thaw—as to whether this was financially sensible, or whether they should instead elect for the woman to undergo a further fresh cycle (where the chances of a birth following may be higher because a clinic would be able to improve a woman's drug stimulation regime having learned lessons from her response to the first cycle).[19] However, they would also have to take into account that a further fresh cycle carries increased risks for the woman, a point addressed by some of our participants below.

We now turn to discuss the freezing policies of the sites we visited, looking first at the site which had a 'minimum-number' policy.

D. Minimum-number Freezing Policy: Site 3

1. The Policy and its Underlying Rationale

At the time we visited Site 3 (our first site, in February to October 2008), the policy was to recommend that a couple should have a minimum of *three* good-quality embryos to justify freezing any from a given cycle. The rationale is well stated by Embryologist 2:

> [T]he policy is we usually … have a minimum of three to freeze for a patient, a reasonable number for the patient. … The reasoning behind that is that we usually have roughly about 65–70% survival rate on the embryos. So if we freeze three, then hopefully we'll have at least two that will survive.

A relevant consideration, explained by Nurse 1, concerns the costs, physical, emotional, and financial, of couples preparing themselves for a frozen embryo transfer. As Embryologist 2 observes: 'If the embryos don't survive the thaw, financially and emotionally and obviously

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[19] Personal communication: Peter Braude, Emeritus Professor, and former Head of Department of Women's Health/Centre for PGD, King's College London.

physically it's quite traumatic for them to go through.' The issue of embryo quality is also, of course, relevant, as explained by Embryologist 4:

> [W]e have very, very seldom frozen, if ever, an embryo that's got a quality of fewer than – that's had a four or five grade. . . . Because they don't survive. They don't do well anyway in a fresh cycle and then if you put them through the trauma of freezing and thawing, they don't do well . . . it's unfair to give patients unrealistic false hope . . . when we know that it doesn't work.

However, a number of interviewees commented on the possibility of *exceptions* to the three-embryo freezing policy. In the first case, as Nurse 1 explains, this would be 'where somebody can never do IVF again', or, as Embryologist 2 notes, 'if they've . . . had . . . a particularly difficult time actually in achieving . . . those embryos . . . so if the patient has had to undergo a very difficult egg collection, say they've had to have general anaesthetic or if the gentleman has been in and had to have . . . a surgical procedure to remove the sperm'. A further exception, noted by Embryologist 4, might be made if there is an embryo of particularly good quality: 'Sometimes if there's less than three, if they're very good quality we'll say, you know, "It's up to you if you'd like to freeze them." Ultimately it is the patient's decision'. A further exception at the time of our interviews, which will increasingly become the norm in women under thirty-five, will be the situation in which only one embryo is to be transferred in order to reduce multiple pregnancy rates. As Embryologist 2 observes in a comment echoed by Embryologist 4:

> What we tend to say to patients who are only having one embryo transferred is that we may decrease that minimum number to two, in the hope that even if just one of them survives, there is a good chance that [the] patient can just go ahead and have another single embryo transfer again. We prefer them not to freeze one embryo but it's the patient's decision at the end of the day who say, against our advice, wants to freeze a single embryo.

Since the time of our interviews, this policy will also have been affected by the clinic's development of the ability to freeze blastocysts, which Embryologist 4 noted would start in the next year or so (that is, 2009/10).

2. The Balance between Professional and Patient Input into the Decision that an Embryo is 'Spare'

Despite the 'minimum-number' freezing policy, several of the interviewees stressed that, at the end of the day, it was a matter of patient choice. For instance, Embryologist 3 observed: 'I think . . . couples should be able to have one embryo frozen anyway if they're prepared

for the fact that they could go through all the setting up and what have you and it not survive. Yes, I think the choice should be down to them finally, yes.' This was backed up for example by Embryologist 4.

Patients can only choose, of course, in the light of good information and are likely to value highly the recommendations of the embryologists that come with that information. However, an important question concerns the strength and status of these recommendations and whether, in effect, they amount to a *decision* that an embryo is 'spare'. Strikingly, Embryologist 4 observed:[20] 'I suppose for the *majority* of patients a *spare embryo is defined by us* because we advise them. But that's what we do, is we advise them, we don't tell them what to do.' Although s/he describes an embryo being defined as 'spare' by embryologists, s/he is also keen to emphasise that this is just 'advice'. However, if a couple were to trust the advice that an embryo is 'spare' (and we do not suggest at this point that this is necessarily inappropriate), then in fact there is *no decision remaining* for them about its possible use in treatment: the only decision would be whether to permit its discard or instead to consent to donation to research. We draw out the important implications of this in the closing stages of this part of the article. The limited scope for deciding what to do with an embryo that has already been defined as 'spare'—that is, 'unsuitable for treatment'—is reinforced by the following observation from Embryologist 2, who in fact says: 'The *decision* to select which . . . embryos are going to be transferred, frozen or donated to research or just allowed to perish, tends to *singly be with the . . . embryologist* that's just observing the embryos in the morning.'[21] Most importantly, this comment suggests that the embryologist might effectively *decide* when an embryo is 'spare'.

Not surprisingly perhaps, patients were reported to vary in their responses to embryologists' 'recommendations' and 'advice'. As Embryologist 7 observed: '[S]ome patients don't want to know the details and they're quite happy for you to decide which are going to be donated to research, which are going to go back [that is, to be transferred] . . . but then you get other patients that question *every little step* of the way.'[22] How easy or otherwise patients might find it to go against recommendations will obviously vary, a point of general relevance in a variety of clinical settings. In this context, the point directly concerns the important question of how much control couples have over the use of their embryos in treatment and the decision that any given one is in fact 'spare'. Strikingly, Embryologist 5 made reference to patients having to be quite assertive in relation to this question of control:

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[20] Our emphasis.
[21] Our emphasis.
[22] Our emphasis.

> [W]e have just frozen one embryo where patients have just been adamant, 'I want this embryo freezing.' You know, we can't say no. It's ... patient choice at the end of the day. And as long as they're happy to accept the risk that this embryo may not survive, then we would freeze it for them.

Embryologist 4, who above noted that 'for the majority of patients *a spare embryo is defined by us*',[23] in fact similarly appears to recognise the place of patient choice, and likewise alludes to a requisite degree of assertiveness on the part of patients seeking to question or override recommendations, saying: 'Ultimately it is the patient's decision. We can just advise them if they *insist* on having one relatively poor embryo frozen, we can tell them we don't think it's a good idea, it's unlikely to survive. But if they want to, it's their embryo, so it's their choice.'[24]

So far, these views suggest an awareness that, in the definition of a 'spare' embryo, there may be a delicate balance at stake between patient autonomy on the one hand and patient trust on the other. The importance of the latter may be particularly apparent in the following account which describes the problems that may be generated when *poor* quality embryos are frozen. Clinician 8, who was obviously deeply concerned for his or her patients, drew attention to the potential problems with 'freezing everything' (of the non-transferred embryos) regardless, as it were, of *quality*, and therefore not, in fact, deciding that some embryos are 'spare' after the initial transfer:

> The ethical purist might say, 'We have to freeze everything.' But then when you see the heartache it causes when this poor woman has been worked up for embryo transfer ... and has had her hopes raised and then you pull those embryos out of freezing, it's not only if they don't survive, it's if they survive but they're falling apart in front of you ... and the embryologist will tell her, 'Look this isn't going to work.' And that's the balance. You're trying to prevent too much of that unhappiness and complete pointlessness really, whilst accepting that in a small number of cases, the embryologist's judgment may be wrong and an embryo that they don't think is worth freezing, might, in some cases, result in a live birth. But, you know, where do you draw the line? Because if you freeze everything you'll get a few more babies per year but an awful lot of unhappiness.

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[23] Our emphasis.
[24] Our emphasis.

However, and not disputing the points made here, a highly important issue in relation to a 'minimum-number' freezing policy is that sometimes embryos that are of *good* quality might not be frozen for future clinical use because there are, in effect, insufficient *accompanying* embryos. Accordingly, such embryos will not be frozen unless a couple somehow elects to disregard the freezing policy. This acutely highlights the possibly *contingent* nature of the decision that an embryo is 'spare'.[25] Strikingly, on the definition of an embryo as 'spare' and the minimum-number element of the freezing policy, Embryologist 7 observed:

> I think it's very easy for an embryologist to explain when a poor quality embryo is spare and can go for research . . . [Y]ou can . . . say, 'It's arrested in its development, or it's very fragmented, the chances of it surviving freezing, thawing . . . .' . . . What is more difficult is for say a patient has four good quality embryos, has two put back and you say, 'Well you've got two left, the unit, to get a good chance with your frozen, normally we would recommend three or more to freeze . . . '. Obviously it's their choice whether they have them frozen, but then that's two good embryos. *So they're not necessarily poor quality and spare, they're actually good quality and spare, but that's harder to explain to the patient.*[26]

In this example, the two embryos that are of good quality but not frozen are defined as 'spare' because the clinic's assessment is that less than 70% of day 3 cleavage stage (non-blastocyst) embryos survive thawing and so, to be reasonably sure to have two embryos to transfer after thawing (in suitable cases), three need to be frozen. There is an alternative, however, which would be to 'bank' embryos: that is, freeze them in batches of less than three. The drawback with this, as Embryologist 7 observes, is that patients would have to pay on each occasion. In this light, this participant speaks of the difficulties of 'getting the balance right for the patient from the money side and their chances' and observes that it is hard 'when a patient's got *one good embryo spare and you*, in effect, *discard it*'.[27] The clinic at Site 3 was in a poorer area of the UK so that cost (given limited NHS provision for treatment services) was a particularly significant issue for many patients. At this point, the interviewer asked: 'So what is a spare embryo in one place, the same embryo might not be a spare embryo in another

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[25] Regarding other empirical work here see also M Svendson and L Koch, 'Unpacking the 'Spare Embryo': Facilitating Stem Cell Research in a Moral Landscape' (2008) 38/1 Soc Stud Sci 93–110, 97.
[26] Our emphasis.
[27] Our emphasis.

place?', to which Embryologist 7 replied 'Yes'. Significantly then, in the case of viable embryos remaining after transfer, whether an embryo is deemed 'unsuitable for treatment' and therefore 'spare' will turn on the freezing policy of any given clinic, subject to patients electing to override this where they have the will and the finances (where they have to pay for freezing themselves) to do so.

In the light of the above discussion, we suggest that the word 'spare' may not be really appropriate to describe these viable embryos. Rather, some embryos are in effect deemed *unusable*—not because of their quality—but because the *lack of additional viable embryos* means that they will not be frozen if the freezing policy is followed. This is highly significant given that ethical guidance relating to and debates regarding the use of embryos for research assume that such embryos are in some straightforward sense 'not required for treatment' and therefore unproblematically 'spare': although the HFEA *Code* stresses 'that only fresh or frozen . . . embryos *not required for treatment* can be used for research', it makes no comment about the decision-making process that results in an embryo being labelled 'spare'.[28] We will begin to develop the legal implications of this below, in preparation for our principal analysis of the legal issues relating to consent to the donation of 'spare' embryos to research in Part 2. For now, as observed some years ago by Søren Holm, the idea of the 'spare' embryo is not in fact a 'natural category'.[29]

E. No Minimum-Number Freezing Policy—Embryo Quality Only: Sites 1 and 2

1. The Policy and its Underlying Rationale

As we have seen, freezing policies are affected by whether a clinic has the facility for blastocyst culture, since there is a very good chance that a blastocyst will survive the thawing process and will have good live-birth potential. The clinics at Sites 1 and 2 (which we visited from May to September 2009, and October 2008 to May 2009, respectively) had the facility for blastocyst culture and freezing, and did not have a policy of only freezing a minimum number of embryos. At Site 1, for instance, the interviewer asked: '[I]t sounds as though for every patient who has any kind of good enough quality, then you freeze?' Research Manager 32 responded: 'Then you freeze, yes.' On the question of freezing or not freezing single embryos, Nurse 39 (Site 1) observed:

> [T]he first thing that springs to mind for me is it only takes one embryo to implant and create a pregnancy, and so if you do have an embryo that you would deem good enough quality to freeze,

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[28] HFEA, above, n 6, our emphasis.
[29] Holm, above, n 7, 64.

> why would you then say to a patient, 'Don't freeze it because you've only got one.' . . . I don't see why it shouldn't be offered, because if your patient has all the information, then it's up to them to be able to say, 'Actually, you know, I don't want to go ahead.'

Genetics Scientist 33 (Site 1) observed: '[A]s far as I am aware, all couples will ask to have any, you know, their other ones, which are suitable, frozen if they've got to the right stage, yes.' Nurse 22 described a similar situation at Site 2:

> [I]t's the clinic policy to recommend freezing even if you only have a single embryo that's of good enough quality, and it's up to you . . . and then we have a conversation afterwards about what to do if you've only got one embryo frozen, maybe try another fresh cycle. . .

The last point alludes to the possibility of 'banking', also discussed for instance by Clinician 30. The policy of freezing only one embryo applies with particular force in relation to blastocysts, given their greater pregnancy potential. Stem-cell Scientist 26 (Site 2) observed: 'But we will freeze, especially one blastocyst, given that we're only putting one blastocyst back . . . '.

2. Patient Choice and the Possible Impact of Donation on Future Treatment

A significant aspect of the freezing policies in both clinics appeared to concern awareness and recognition of the importance of patient choice. For instance, Stem-cell Scientist 41(Site 1) observed:

> [I]f we took a fresh embryo, like a surplus one, and we say we're not going to freeze this, so we're not giving them the chance I suppose . . . and we say to them, 'Here's your choice, we can't put it back because you've already got however many, and that's our policy. So it's either destroy or research.' Then that's not giving . . . the patient a sort of choice.

On the question of patient choice and the developing role of patients in decision-making, there was discussion in an EDG at Site 1 of the way in which, in the past, patients might have deferred fully to the embryologists, saying for instance, as Embryologist 50 put it: 'Oh you're the experts, I'll run with you', but '[n]ot now' since '[a] lot of people' use the Internet to gain information about their treatment. With a view to patient choice, there was also evidence of a willingness to freeze embryos with *less than clear potential* on occasion. Embryologist 26 (Site 2) observed:[30]

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[30] Our emphasis.

> But something that is just outside of, just slightly outside of what we normally do and the patient felt very strongly about it . . . because *they're theirs*, then it would be very difficult to say 'no' – particularly since we can't say absolutely that they won't survive, and absolutely that they wouldn't implant.

Notably apart from concerns about the importance of patient choice in relation to embryos, there was also a significant concern about the possible impact on a patient's treatment options if that choice is reduced, including a clinical concern that a woman should not have to undergo any potentially *avoidable* cycles of IVF. This is put well by Nurse 22 (Site 2):

> But you may be, by not freezing an individual embryo, automatically reducing the choice to patients, in that if they don't get pregnant, their only choice of treatment then is another fresh cycle. And if you feel very unwell through that cycle, and you get OHSS [ovarian hyper-stimulation syndrome], you might well feel that you wish that that embryo had been frozen on your behalf.

The clinical and ethical issues associated with possibly *avoidable* cycles of treatment are also evident in a comment from Clinician 30 (Site 2):

> I think anything that has got a reasonable chance of pregnancy ought to be kept cryopreserved. The reason is, it's less risky for the woman to have a treatment cycle with frozen and thawed embryos than to go through ovarian stimulation again and egg collection again and put herself at risk. So, yes, you know, in terms of, you know, do no harm and do good. It fits in with both really . . .

Significantly then, one impact of *not* freezing a remaining single good-quality embryo, should the fresh cycle fail, is that the woman will have to undergo another fresh cycle in order to try to become pregnant, although there is always the risk, of course, that a single frozen embryo will not survive the thawing process (to recap, a risk of about 30% for a non-blastocyst embryo). Alternatively, even if a given cycle does give rise to a live birth, should the couple seek a further child and if a single good-quality embryo had not been frozen from the first cycle, there would be no frozen embryo to try to thaw and transfer, so that a further stimulation cycle would be the only option. Another highly important reason to give couples choice about freezing even one reasonable-quality embryo is that nothing can be presumed about the way a subsequent cycle will go. Stem-cell Scientist 19 (Site 2) observed: '[G]oing through another cycle of ovarian stimulation, it might not happen that good again or it might not happen at all . . . '.

Participants' use of phrases such as 'because they're theirs' (Site 2), 'it's patient choice at the end of the day', or 'it's their choice' (Site 3) or 'it's up to them' (Site 1) appear to reflect awareness, not just of the biological connection between the embryo and either one or both parents (except where an embryo is formed entirely from donor gametes), but also some sense that patient choice as to freezing would be supported by the law. Is this so?

III. PATIENT CHOICE, FREEZING AND THE LAW

The legal position is not in fact clear-cut and requires some interpretation. On the question of storage, section 8(2) of the HFE Act 1990 (as amended) provides:

> An embryo the creation of which was brought about *in vitro* must not be kept in storage unless there is an effective consent, by each relevant person in relation to the embryo, to the storage of the embryo and the embryo is stored in accordance with those consents.

The Act does not stipulate that a person can *require* that their embryos are stored. Indeed, as a matter of common law, a person cannot *require* treatment, including assisted reproduction treatment, where a clinician considers that treatment is against his or her clinical interests.[31] However, if the remaining good- or reasonable-quality embryos left after embryo transfer are not stored, then, unless there is consent to another purpose—including donation to research—that embryo must be allowed to perish.[32] On the question of allowing an embryo to perish, section 17(1) of the amended 1990 Act states that '[i]t shall be

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[31] This was a central point in the Court of Appeal decision in *Re J (A Minor) (Child in Care: Medical Treatment)*, [1993] Fam 15 (which concerned potential non-treatment of a severely brain-damaged child). Lord Donaldson MR held that a court, in exercising its inherent jurisdiction, should not require a clinician 'to adopt a course of treatment which in the *bona fide* clinical judgment of the practitioner concerned is contra-indicated as not being in the best interests of the patient' (at 26–7). The principle is reflected in jurisprudence relating to adults in the Court of Appeal decision in *Regina (Burke) v General Medical Council (Official Solicitor and others intervening)* [2006] QB 273 (which concerned proceedings brought to obtain clarification as to the circumstances in which treatment might lawfully be withdrawn from an adult with a congenital degenerative brain condition, by means of a judicial review of guidance issued by the General Medical Council). Lord Phillips MR held that '[a]utonomy and the right of self-determination do not entitle the patient to insist on receiving a particular medical treatment regardless of the nature of the treatment' (at para 31).

[32] Embryos cannot be kept longer than 14 days under the HFE Act 1990 (as amended), s 3(4).

the duty of the individual under whose supervision the activities authorised by a licence are carried on . . . to secure . . . (c) that proper arrangements are made for the keeping of . . . embryos . . . [and] for the disposal of . . . embryos . . . that have been allowed to perish'. The question that arises here is who in law can 'allow' a good- or reasonable-quality (or at a minimum not non-viable) embryo to perish when a couple is currently in the process of treatment. We argue that, as a matter of interpretation, including with reference to the background common law principle that a clinician may decline to treat where this is considered against the interests of the person seeking treatment, those treating a couple in an assisted reproduction clinic cannot make the decision to 'allow' an embryo to perish unless they consider that no further treatment is advisable for this couple and the couple has not given consent for another purpose. As for other purposes, there can only be consent to research, under the *Code's* interpretation of the Act, where an embryo is 'not required for treatment'.[33] We argue here that any good- or reasonable-quality embryo of a couple seeking treatment, who would not of course know the result of their current cycle at the point of the donation of a fresh embryo to research, *could not be such an embryo unless the couple has agreed not to freeze it*.

So, while the legal position is explicitly concerned with the *use* to which embryos are put, implicit in this must be a certain degree of control regarding *which* embryos can be used in the treatment of the couple: arguably, it cannot be the case that a couple can be denied the use, especially of good quality but also of other viable embryos in treatment either in a fresh (subject to policy guidance as to the number that may be transferred in any given case) or a subsequent frozen cycle, unless those treating a woman consider for clinical reasons that further treatment at *any* stage is inadvisable. Sometimes, cycles are abandoned because of ovarian hyper-stimulation syndrome (OHSS). However, even in these circumstances, other things being equal, it will be possible to freeze any embryos created for future possible use rather than continue the current fresh cycle.

IV. CONCLUSIONS

This part of our article has analysed data from three UK IVF sites involved in the provision of embryos to research, including stem-cell research, in order to show the delicate and sometimes contingent nature of the decision that an embryo is 'spare' and to consider aspects of the relationship between professional and patient input into this decision.

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[33] HFEA, above, n 6.

Once the decision has been made that an embryo is 'unsuitable for treatment', therefore 'spare', the only decision remaining is whether it should be discarded or donated to research or training (where suitable for the latter purposes). The question of consent to the use of embryos in any given research project, including stem-cell research, has its own set of ethical and legal issues pertaining to the purposes of the research. However, our focus here has been on the way in which an embryo *reaches the point when it might pass from the treatment to the research context*. The defining moment is when the decision is made that an embryo is 'unsuitable for treatment', or 'not required for treatment' (under the HFEA *Code*) and so 'spare'.[34] As noted, once an embryo has passed from the clinic to the research laboratory on this basis, it will no longer be available for a couple's use in treatment. In effect, this means that at the point when it is decided that an embryo is 'not required for treatment', a couple will be consenting to that embryo's disuse in treatment. Most significantly, then, *to consent to an embryo being 'spare' is to consent to its disuse in treatment*. Subject to a couple's consent 'in principle' to donation to research and to the specific terms of any given research project, this will be closely followed by consent to donation to research.

In this light, patient input into the decision that an embryo is 'spare' now requires analysis with reference to the key elements of the law of consent, namely information as to nature and purpose, voluntariness and capacity. We engage in this in Part 2 below, referring also to elements of the wider legal framework and relevant codes of practice. Overall, our aim is to show that when fresh, rather than frozen embryos are 'let go' as spare and subsequently donated for research (which may particularly occur with minimum-number freezing policies but also in other ways), in some circumstances the initial consent to an embryo's disuse in treatment—to its 'spareness'—could be of uncertain quality (in the sense that there is a risk that a couple might have decided differently), or could in fact be invalid. While these latter occasions are likely to be rare, more generally, our analysis will highlight the need to attend to ways of enhancing the quality of the process of consent to an embryo's disuse in treatment and, subsequently, to its donation to research. Further, when fresh embryos pass from the clinic to the research laboratory (rather than being frozen for possible subsequent use in treatment) there is the potential, on occasion, for women to have to undergo what should have been *avoidable* additional fresh cycles of IVF and so for their consent to these to be compromised. Accordingly, there may

[34] HFEA, above, n 6.

be effects on the reproductive treatment options of couples seeking the birth of children through assisted reproduction treatment.

PART 2: HOW CAN WE ENHANCE THE QUALITY AND PROTECT THE VALIDITY OF CONSENT?

I. INTRODUCTION

The donation of 'spare' human embryos to research, including stem-cell research, requires the consent of the donating couple.[35] In Part 1 above, we drew attention to the delicate and sometimes contingent nature of the decision that an embryo created for treatment purposes is 'spare' and the relationship between professional and patient input into this. We concluded that consent to the donation of such an embryo to research entails, first, consent to the disuse of that embryo in treatment on the basis that it is 'spare'. This is a stage in the process of the donation of a 'spare' embryo to research that is not directly covered by the HFE Act 1990, as amended by the HFE Act 2008, or the HFEA's *Code of Practice*: whilst the provisions of the HFE Act 1990 (as amended) cover consent to the *use* of an embryo in treatment or research, they do not deal explicitly with the significant 'flipside', namely consent to its *disuse* in treatment (rather than withdrawal of consent for any purpose *per se*); and the HFEA *Code* assumes a straightforward notion of an embryo that is 'not required for treatment'.[36] Having identified this important initial stage in the process of consent to the donation of a 'spare' embryo to research in conclusion to Part 1, in Part 2 we now analyse the idea of consent to an embryo's disuse in treatment on the basis that it is 'spare' with reference to the legal elements of consent, namely information as to nature and purpose, capacity and voluntariness.

We argue that there are in fact three related consent processes in play, of which the principal one concerns consent to an embryo's disuse in treatment. If the quality of this first consent is compromised, in turn this will impact on the quality of the consent to the donation of that 'spare' embryo to research, followed by the quality of consent to future cycles of assisted reproduction treatment where these are needed as a result of a donation decision. Our aim is to identify possible, though hopefully rare, legal flaws in the process of consent to the donation of 'spare' embryos to research and, more generally, to make a

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[35] The relevant provisions of the HFE Act 1990, as amended by the HFE Act 2008, above, n 1, were introduced in Part 1 and will be discussed further here.

[36] HFEA, above, n 6, para 22.7(h), our emphasis. The same wording was used in the 7th edition (2007) para G.5.13.1(b); the 6th edition (2003) used the phrase 'surplus to treatment', para 5.8(ii).

recommendation that should enhance the quality of that consent. Apart from being important in its own right, this would reduce the risk of potentially avoidable fresh treatment cycles for women trying to conceive a child and protect, as much as possible, the reproductive treatment options of couples needing assisted reproduction treatment. Our discussion has a particular bearing on the question of whether and if so to what extent it should be permissible to request fresh, rather than frozen embryos (that are coming to the end of their statutory storage term)[37] for research. In this sense, it is particularly relevant to the donation of embryos to stem-cell research, since (as noted in Part 1) there is a debate as to whether fresh embryos are the most useful for this kind of research.[38]

We outlined our qualitative research into three UK IVF sites involved in the provision of embryos to research, including stem-cell research, in Part 1. We make further reference to some of this data in Part 2, as well as to empirical research conducted by others into practices that, in our view, particularly highlight the need to attend to the process of consent to an embryo's disuse in treatment.

In Section II, we analyse the legal elements of this consent with reference to the common law, the HFE Act 1990 (as amended) and relevant ethical guidance, notably in the HFEA's *Code* and the Medical Research Council (MRC) Steering Committee's *Code of Practice for the Use of Human Stem Cell Lines*.[39] The central connecting thread is the impact that the *timing* of the request for the donation of 'spare' embryos to research may have on the satisfaction of the elements of consent. In effect, this is an issue relating to whether fresh rather than frozen embryos may be sought, and may then pass, from the clinic to the research laboratory.

In Section III, we argue for our key recommendation which concerns whether, and if so when, it should be permissible to request fresh embryos for research.

II. CONSENT TO AN EMBRYO'S DISUSE IN TREATMENT

A. The HFE Act 1990 as amended by the HFE Act 2008 and the Legal Elements of Consent

The consents involved in assisted reproduction treatment are governed by a mixture of common law and statute under the HFE Act 1990 (as amended). When a couple seeks treatment, the woman is the patient (she will be subject to a certain drug regime and egg retrieval

[37] As noted earlier, this is now 10 years in the UK under the HFE Act 1990 (as amended), above, n 1, s 14(4).
[38] Above, n 3.
[39] MRC Steering Committee, above, n 6.

procedures) and she must consent to that treatment, the validity of which is assessed by the common law requirements of capacity, information as to nature and purpose and voluntariness.[40] We outlined the statutory provisions on consent in Part 1, noting that these require a couple's consent in writing for any of the stipulated purposes and that compliance with these is a condition of a clinic's licence under section 12(1) of the amended 1990 Act.[41] We argued above, on the basis of the consent and other provisions of the Act and with reference also to the common law, that implicit in this legal requirement of consent to the use of embryos in treatment must be a certain degree of control regarding *which* embryos can be used in treatment, including by freezing. This is because it cannot be the case that a couple can be denied the use especially of good-quality embryos, but also of any viable embryo, either in a fresh cycle (subject to HFEA guidance as to the number that may be transferred in any given case) or a subsequent frozen one, unless a clinician considers that further treatment at *any* stage is inadvisable.[42] We further develop this analysis here.

1. Capacity

All adults (those over 16) are presumed competent to consent to treatment and research in English law. Under section 2 of the Mental Capacity Act 2005 (the MCA 2005), a patient lacks capacity if s/he is 'unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain'. Section 3 stipulates that this will occur where a person is 'unable – (a) to understand the information relevant to the decision, (b) to retain that information, (c) to use or weigh that information as part of the process of making the decision, or (d) to communicate his decision (whether by talking, using sign language or any other means)'.

The issue of capacity may be relevant to the timing of consent to an embryo's disuse in treatment, coupled with its availability for research, in that the decision-making capacity of some women at an advanced stage of ovarian stimulation may be impaired. However, in the Court of Appeal in *Re M.B.* (*Adult: Medical Treatment*), Lady Justice Butler-Sloss stressed that although temporary factors such as confusion, shock, fatigue, pain, or drugs *may* completely capacity, others must be satisfied

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[40] Regarding each of these elements, see, respectively, *Re M.B.* [1997] 8 Med LR 217, *Chatterton v Gerson* [1981] 1 All ER 257, *Re T (Adult: Refusal of Treatment)* [1992] 4 All ER 649.

[41] See also HFEA, above, n 6, Licence conditions T57, R18.

[42] *Re J (A Minor) (Child in Care: Medical Treatment)* [1993] Fam 15; *Regina (Burke) v General Medical Council (Official Solicitor and others intervening)*, above, n 31.

that these factors are so powerful that the ability to decide is not present (that is, that capacity is truly eroded).[43] Despite this caveat, it may be with a view to the issue of capacity (and also perhaps to that of voluntariness, introduced below) that the MRC Steering Committee's *Code* recommends that '[d]onors should be approached as early as possible, usually before ovary stimulation, to allow sufficient time to think issues over'.[44] The possibility that decision-making capacity could be affected, and conceivably negated, may be evident in comments from Nurse 1 (Site 3) with regard to seeking consent during treatment:

> The patient's got to make their decision in a cold situation and not . . . with all the emotions going round their heads when they're at egg collection and they're full of hormones and they're full of expectations and anticipation and they've got a vision of this baby that's coming . . . that's not a time for decision making.

The negation of a woman's capacity as the result of her drug stimulation regime is clearly possible, with the result that her part of the consent to an embryo being 'spare', and so removed from the treatment context and donated to research at this time, could be invalid. However, such a scenario will probably be rare and what may be more likely is that decision-making capacity could be affected rather than actually negated. For instance, as the above quote illustrates, it may be that a woman finds it very difficult to think about a request related to research at a time when her focus, as a patient, is on treatment. In this light, since there is always a risk of capacity being affected and, more remotely, of an actual negation of capacity, we argue that seeking consent to the donation of 'spare' embryos to research during a treatment cycle is inappropriate, subject to some exceptions that we detail later. The remainder of our analysis concentrates on the legal elements of information and voluntariness. After introducing these, we subsequently analyse their place in the process of consent to an embryo's disuse in treatment.

2. Information

To be informed about treatment and research sufficient for the legal notion of consent, a patient must be informed of its nature and purpose.[45] Generally speaking, consent to research could entail

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[43] *Re M.B.* above, n 40, 224.
[44] MRC Steering Committee, above, n 6, para 9.1.
[45] Above, n 40. There is no English case law that can be cited for the requirements of a valid consent to research. However, it is commonly understood that the requirements of capacity, information, and voluntariness are also relevant to the validity of consent to research. For a recent statement of this, see eg Nuffield Council on Bioethics: *Human Bodies: Donation for Medicine and Research* (Nuffield Council on Bioethics, London 2011),

consent to taking a trial drug or the donation of bodily tissue (to which the Human Tissue Act 2004 would be relevant). Here, we are concerned with the donation of an entity (an embryo), created for the purpose of assisted reproduction treatment, to research. There is therefore a physical (in the form of the embryo) and conceptual link (by means of the processes of consent involved) between the treatment and research domains. In this light, we argue that there are three related consent processes at stake, of which the principal one concerns consent to an embryo's disuse in treatment on the basis that it is 'spare'. The second concerns consent to the donation of that 'spare' embryo to research and the third may concern consent to one or more additional fresh cycles of treatment. The reason for the third aspect is that assisted reproduction very often involves more than one round of ovarian stimulation (where a first round is unsuccessful) and will almost always do so if more than one child is sought.[46] In any event, at the point when a fresh embryo may be released for research, the outcome of the current cycle will not yet be known, so that the possibility of future treatment being needed is highly relevant. For these reasons, the 'treatment' in question is best viewed as a 'treatment process' that may well entail more than one cycle of ovarian stimulation. We are concerned, then, with the information of relevance to that *treatment process* as a whole.

Turning specifically to the research context, and moving beyond the baseline of the *legal* requirements for consent to aspects of the relevant ethical codes, the *Declaration of Helsinki*, for instance, refers to consent that is 'adequately informed' as to a number of factors, including the 'potential risks of the study'.[47] The General Medical Council advises, in part: 'You must give people the information they *want or need* in order to decide whether to take part in research ... You must not make assumptions about the information a person might want or need, or their knowledge and understanding of the proposed research project';[48] and that '[i]f you are involved in designing, organising or carrying out research, you must ... put the protection of the participants' interests first'.[49] Ethically speaking, these statements indicate the particular importance of information in the research context, though English case law has not dealt explicitly with consent to research.

Moving directly now to the donation of embryos to research, including stem-cell research, the HFE Act 1990 (as amended) requires that

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para 2.7. See further below regarding the ethical requirements for consent to research.

[46] The caveat 'almost' allows for the case of a twin birth.

[47] *Declaration of Helsinki* (World Medical Association, 1964, and amended by the 59th WMA General Assembly, Seoul, October 2008) para 24.

[48] GMC, *Consent to Research* (2010) para 4, our emphasis.

[49] GMC, *Good Medical Practice* (2006) para 71.

'[b]efore a person gives consent . . . (a) he must be given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and (b) he must be provided with such relevant information as is proper'.[50] Interpreting this requirement, the HFEA *Code* advises, in part, that 'before a person consents to donating embryos . . . for research . . . they should be given: (a) enough information to understand the nature, purpose and implications of their donation'.[51] The HFEA *Code* lists the information that potential donors should receive prior to giving consent.[52] There is an additional list where stem-cell donation is concerned.[53] For research in general, information should be given about, for example: '(a) the specific research project and its aims . . . (c) whether the embryos will be reversibly or irreversibly anonymised, and the implications of this'.[54] Whilst important in their own right, these points do not concern us here. We are, however, concerned with two crucial points of general relevance to donation to research, including stem-cell research:

> (f) that donating gametes or embryos to research in the course of treatment services *will not affect the patient's treatment* in any way . . . (h) that only fresh or frozen gametes and embryos *not required for treatment* can be used for research.[55]

We drew attention to the phrase 'not required for treatment' in Part 1, highlighting that the *Code* makes no mention of the decision-making process by which an embryo comes to be labelled as such, and therefore 'spare', and so identifying the need to analyse the attendant process of consent, which we undertake here.[56] Here, we will also consider whether there is scope for paragraph (f) to be breached when fresh embryos are donated to research, in the sense that the decision to donate could on *some* occasions affect a woman's treatment, understood as the 'treatment process'.

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[50] HFE Act 1990 (as amended), above, n 1, Sched 3, para 3(1).
[51] HFEA, above, n 6, 'Interpretation of Mandatory Requirements', Box 22B.
[52] Ibid, para 22.7.
[53] Ibid, Licence condition R20.
[54] Ibid, para 22.7.
[55] Ibid, our emphases. The 7th edition, above, n 6, stated 'that research will not affect the treatment cycle; and . . . where gametes or embryos are being donated to research in the course of treatment services, that this will not compromise the treatment cycle', para G.5.13.1(c), (d); the same wording is used in the 6th edition, above, n 6, para 5.8 (iii), (iv).
[56] In the form for donation to stem-cell research, 'Consent Form: Patient Consent to Research: Derivation of Human Embryonic Stem Cell Lines', the phrase 'embryos that are surplus/unsuitable for treatment' is also used. S Franklin, C Hunt, G Cornwell, V Peddie, and others, 'hESSCO: Development of Good Practice Models for hES Cell Derivation', (2008) 3(1) Regen Med 105–16, 114.

In the light of the above, *if* fresh embryos were to be sought for research, what information should patients be given in addition to the points in the relevant codes? Since we are concerned, first, with consent to the disuse of an embryo in treatment, part of this question concerns what a patient must be informed of in order to consent to that disuse. Accordingly, we argue that patients would have to be informed: that the advice is that a given embryo is 'unsuitable for treatment' or 'not required for treatment' (the phrase in the HFEA *Code*) and the reasons for this, including on the grounds of a clinic's freezing policy (discussed below); that they nevertheless have the option to freeze viable non-transferred embryos if they wish (assuming that there are no clinical contraindications regarding further treatment, which is unlikely in relation to a frozen-replacement cycle); that occasionally viable embryos judged to be of poor quality do in fact have good pregnancy potential; and that where no viable embryos are frozen from an initial cycle any further treatment will necessarily entail a further fresh cycle rather than a frozen-replacement one, so that donation will affect the treatment process as a whole. When informed of this last point, it seems unlikely that a couple would consent to the donation of fresh viable embryos to research, a crucial point to which we shall return, rather than request that those embryos be frozen (subject to any financial obstacles or other concerns). This is because, where they are able to freeze embryos, should they need further treatment, they would then have the option *either* of a frozen replacement cycle *or* a further fresh one (depending on their appraisal of information regarding thawing, a clinic's success with frozen-replacement cycles, 'banking', and respective costs). We will add some important elements to this 'information list' as our analysis unfolds.

3. Voluntariness

Consent to treatment or research is only valid if voluntary.[57] The little English case law on point concerns a patient's will being overborne in some way. In the leading case of *Re T (Adult: Refusal of Treatment*), the Court of Appeal explored the notion of undue influence and the way it might negate voluntariness, analysing the effect of influence with reference to the strength of will of the patient (for instance, if tired or in pain s/he may be less able to resist), the relationship between the persuader and the patient and the types of arguments used.[58] It is not easy to prove that voluntariness is negated in the treatment context, as a case from the assisted reproduction context shows.

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[57] Above, n 40.
[58] *Re T*, above, n 40.

In *U v Centre for Reproductive Medicine*,[59] a husband had signed the clinic's consent form on storage and disposal of sperm which advised that the clinic did not agree with posthumous use of sperm but that if necessary '[p]ossible transfer' to another clinic could be discussed. He also signed an HFEA form agreeing, amongst other things, that his sperm could be used posthumously. The next day his sperm was surgically extracted (due to a prior vasectomy) and frozen. Some weeks later, the couple attended the clinic to discuss further his wife's treatment, which was about to start. At that meeting, he was suddenly and unexpectedly asked to withdraw his consent to posthumous use by a nurse on the grounds of the clinic's policy, which he then did. A few days later, his wife's treatment began. The first cycle was unsuccessful and they were due to try again but the husband died. The clinic sought advice as to the legal position and the wife argued that her husband's withdrawal of consent to posthumous use resulted from undue influence. In the Family Division, Lady Justice Butler-Sloss found that the nurse had not made her request 'at all sensitively'; that she 'gave to the wife the impression that there would be at least a pause in the treatment cycle with the possibility that it might be interrupted or even brought to a halt' if her husband did not change his mind; and that '[h]e succumbed to the firmly expressed request of Miss Hinks [the nurse] and under some pressure', likely not thinking this part of the form would ever be relevant.[60] However, despite the 'considerable'[61] pressure, she held that 'it is difficult to say that an able, intelligent, educated man of 47, with a responsible job and in good health, could have his will overborne so that the act of altering the form and initialling the alterations was done in circumstances in which Mr U no longer thought and decided for himself'.[62] In short, giving attention to Mr U's characteristics generally, she held that the pressure was not enough to constitute undue influence, for which more had to be shown. The question, as she put it, was whether he changed his mind 'under compulsion'.[63] However, she also found the case was 'finely balanced' and so gave leave to appeal.[64] The Court of Appeal agreed with her decision. Lady Justice Hale (as she then was) observed:

> The test these days, [counsel for Mrs U] says, is not whether Mr U's will was overborne but whether he had a real choice on that day to refuse to alter the form. In the end, he argues, it comes down to

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[59] [2002] EWCA Civ 565.
[60] [2002] EWHC 36 (Fam), para 22.
[61] Ibid.
[62] Ibid, para 28.
[63] Ibid.
[64] Ibid, para 2.

> what Mr U really wanted . . . That is not, however, the question in this case. The question is whether the Centre has an effective consent for the continued storage and later use of these sperm. Without such consent it is unlawful for them to continue to keep it. On the face of it the Centre does not have such consent in this case. There could scarcely be a more obvious way of withdrawing consent than changing the very document upon which it is recorded in the presence of a representative of the Centre and authenticating it for her.[65]

With respect, it is not clear that there is sufficient attention here to the quality of the decision Mr U made to change his mind, especially since she observed earlier that '[t]hey had already committed themselves, mentally, emotionally and financially, to the course of treatment. The husband had already undergone his part in it. The wife was about to begin hers. This was a considerable ordeal and they were both very vulnerable'.[66] The decision is supported by Andrew Grubb, who cites Lady Justice Hale's observation that '[s]adly, it is only with the benefit of hindsight that he might have wished to do otherwise'.[67] By contrast, it is criticised by Shaun Pattinson, who argues that the husband's position and characteristics were 'likely to be weakened by the degree of trust typically vested in medical opinion and the emotional vulnerability of most patients'; and that, since Mr U was in a position where the costs of not changing his official statement of views appeared high and the consequences very remote, 'even a small amount of pressure [would have been] sufficient to overbear [his] will'.[68] The Court of Appeal also emphasised that a court should be slow to find undue influence where that would provide a clinic with a consent that it would not otherwise have.[69] In fact, we are likewise concerned with the idea of a clinic being provided with a consent that it would not otherwise have, moreover a consent to an embryo created for *treatment* purposes being 'spare' and available for *research*, and this is a reason for particular attention to the quality of the consent process. Overall, the *U* case raises the question of whether the idea of 'compulsion', as understood by these judges, is sufficiently sensitive to the circumstances of this kind of case.

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[65] Above, n 59, paras 22 and 23.
[66] Ibid, para 21.
[67] A Grubb, 'Infertility Treatment: Posthumous use of Sperm and Withdrawal of Consent' (2002) 10(3) Med L Rev 326–7, 327, citing above, n 59, para 28.
[68] S Pattinson, 'Undue Influence in the Context of Medical Treatment' (2002) 5(4) Med L Int 305–17, 309, 310.
[69] Above, n 59, paras 28 and 26, respectively.

Voluntariness may in fact also be affected by factors beyond those such as 'undue influence'. For example, when the President's Commission looked at this issue, it emphasised not just that treatment should not be coerced, but also that manipulation of information—through misrepresentation, fraud, or distortion—may affect voluntariness.[70] Whilst the former examples imply intention, the latter may occur unintentionally. We aim to show that because of the timing of the consent process when fresh embryos are sought for research, unintentional flaws in information may also affect voluntariness in various ways.

Codes governing research also emphasise the need for a willing participant. Standard worries about voluntariness in this context concern the vulnerability of patients and, potentially, their sense of gratitude to their clinicians.[71] The *Declaration of Helsinki* contains a warning about patients' dependency.[72] Here, we note such concerns with specific reference to the situation of IVF couples, a point to which the law should also be sensitive.

B. Information, Voluntariness, and the Timing of Consent to an Embryo's Disuse in Treatment

In this section, we analyse possible flaws in the principal consent process with which we are concerned, that is, consent to the disuse of an embryo in current treatment on the basis that it is 'spare'. We analyse the possible impact of these flaws on the two other consent processes, namely consent to the donation of that 'spare' embryo to research and consent to future cycles of treatment, in Section C below.

1. Requests for Donation to Research before or during Treatment

When interpreting the HFE Act 1990 (as amended), the HFEA *Code* provides that:

> The centre should give anyone . . . considering donation . . . enough time to reflect on their decisions before obtaining their consent. The centre should give them an opportunity to ask questions and receive further information, advice and guidance . . . If the possibility of donating . . . embryos . . . for research . . . arises during the course of treatment, the centre should allow potential donors

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[70] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Making Healthcare Decisions: The Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship,* Volume 1: Report (Washington, US Government Printing Office 1982) 66–8.

[71] E Jackson, *Medical Law: Text, Cases and Materials* (2nd edn, Oxford University Press, Oxford 2009) 490.

[72] Above, n 47, para 26.

> enough time to consider the implications and to receive counselling before giving consent.[73]

The HFEA *Code* clearly considers that donating embryos to research may arise 'during the course of treatment' and cautions about the need for sufficient time for reflection on the part of donors in these circumstances, which it appears to consider to be achievable. However, as the following discussion shows, seeking consent *during* treatment has the potential to impact negatively on the consent elements of information and voluntariness. Although the provision in the MRC Steering Committee's *Code* that '[d]onors should be approached as early as possible, usually before ovary stimulation, to allow sufficient time to think issues over' (cited above) is commendable, our discussion shows that seeking consent *before* treatment is also problematic.

At the clinics we visited it was nurses, clinicians, or stem-cell coordinators who sought 'in principle' consent before treatment began, using a standard HFEA form. Willing couples would then be approached later in an additional process of consent to a specific research project. The key question, of relevance to the debate about the donation of fresh embryos to research, is how much later a second consent—one that removes an embryo from possible therapeutic use—should take place.

At Site 3, Embryologist 2 advised that the policy was to raise the topic of donation 'as early as possible so that the patients have time to think about possible research and ask questions'. However, Embryologist 7 observed: 'Patients tend to get confused. So it's making sure that you don't have information overload and ... make them worry or unduly stressed.' Relevant to this is the question of the real focus of couples' attention at this time. Nurse 21 (Site 2) observed that at most one in ten couples had talked to each other about freezing and research when they 'come back', saying:[74] 'They're not really interested. They are just *focused on coming through for treatment,* getting a date, starting ... *they will do whatever you say.*' This was supported by Nurse 3 from that clinic.

In short, one highly significant worry about any consent *pre*-treatment is that patients have to deal with a great deal of information at this time that is relevant to their treatment, the issue on which they are naturally focused. For this reason, the information element of any consent to an embryo's disuse in treatment and so to its donation to research may be compromised in a way that we summarise shortly.

We now turn to the idea of consent to donation *during treatment*, including a 'final' consent to the donation of fresh embryos to research. Of

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[73] HFEA, above, n 6, paras 5.6 and 5.7.
[74] Our emphasis.

relevance to voluntariness may be Nurse 1's comments (above, Site 3) relating to 'emotions going round their heads when they're at egg collection and they're full of hormones', given that the drug regime could in some circumstances negatively impact on the strength of a woman's will and given the relationship of the person requesting consent (professional, even if from the research laboratory rather than the clinic) to the patient. Indeed, Counsellor 6 (Site 3) was concerned that patients might want to be thought of as 'good patients', a point of general relevance that we identified earlier, observing that 'taking consents is linked in to being a good patient and doing what you think the clinic maybe wants you to do'. A potential problem with any final consent before egg collection is brought out by Embryologist 20 (Site 2), who noted that 'once they form embryos . . . the patients do form a bond with those embryos, much more so than they would with just eggs'. The point here, which relates first to the information element of consent, is that a couple may feel differently when embryos, rather than eggs and sperm, actually exist and arguably this is an additional point of which they should be advised. In line with this approach, Embryologist 5 (Site 3) spoke of 'giv[ing] them the information on the day of egg collection, so the patients have still got a few days to think about things and change their minds', with final consent being sought on the day of embryo transfer. However, we question whether patients are able to think sufficiently clearly at either of these critical times about the donation to research of what is, for them, an important *finite* resource. Rather, as Embryologist 7 (Site 3) reminds us: '[A]ctually, you know, *patients are just focused on their treatment*. They're here to get pregnant and that's the priority and it should be the clinic's priority'.[75] The idea of a final consent at embryo transfer was in fact rejected by Counsellor 28 (Site 2) who observed: '[I]t would be a dilemma for couples, who are in a very emotionally charged situation to make a decision then . . . [The embryos are] . . . very special, and I think that is a *very hard and important decision to make before they just let them go*'.[76]

In short, there is the potential for either or both of the information and voluntariness elements of consent to be affected when consent to the donation of 'spare' embryos to research is sought either before or during treatment, as will necessarily be the case when *fresh* embryos are sought for research. The effect could constitute a reduction in the quality of consent (in the sense that there is a risk that a couple might have decided differently) or an actual negation of the validity of consent. Whilst the common law doctrine of consent requires information

[75] Our emphasis.
[76] Our emphasis.

to be given as to nature and purpose, it is in fact silent on the question of a patient's actual understanding. However, from a statutory viewpoint, the HFEA *Code*, interpreting the amended 1990 Act, stipulates:

> The centre should ensure that anyone giving consent declares that: (a) they were given enough information to enable them to understand the nature, purpose and implications of the . . . donation (b) they were given a suitable opportunity to receive proper counselling about the implications . . . (d) the information they have given in writing is correct and complete.[77]

In other words, the HFE Act is interpreted by the HFEA as requiring a 'check' on the information given and the understanding that followed it. Overall, the possible hazards of consent during treatment are well captured by Clinician 30 (Site 2):[78] 'I think the consenting issue . . . is a major issue in terms of getting embryos for research . . . getting it right . . . [*I*]*f you are unscrupulous, you can just get them to sign . . . after a minimal amount of information and . . . they will sign it without having understood the full implications of it*.' In sum, where information is given in circumstances such as those described above—when couples are in fact focused on their *treatment*—the quality of consent to research may be foreseeably compromised and there could be grounds, on occasion, to question the validity of consent. Moreover, the risks of such effects on consent are *unnecessarily* run, since frozen embryos that are no longer wanted for treatment and, preferably, are coming to the end of their statutory storage term could be sought instead, as discussed further in Section III. (Of course, couples can choose a storage term of less than the statutory maximum, and can then elect to extend the term if they wish.)

In the light of the above discussion, we draw attention to a study (published in 2004 and relating to research conducted in 2002–2003) about donation of embryos to research at the Newcastle Fertility Centre. The paper is not concerned with consent in the way that we are, but rather with examining the donation rates of fresh embryos with a view to increasing these.[79] At the time of the study, the clinic had a freezing policy that required a minimum of four 'spare' embryos, although if these criteria were not met, requests for freezing

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[77] HFEA, above, n 6, para 5.9. This further develops the requirements in 'Interpretation of Mandatory Requirements', Box 22B, above, in the quoted text preceding n 51, and in paras 5.6 and 5.7, above in the quoted text preceding n 73.

[78] Our emphasis.

[79] M Choudhary and others, 'Demographic, Medical and Treatment Characteristics Associated with Couples' Decisions to Donate Fresh Spare Embryos for Research' (2004) 19/9 Human Reproduction 2091–6.

were 'considered'.[80] Couples received information, the HFEA leaflet on embryo donation for research and a consent form (explaining the research study, which was either stem-cell or preimplantation genetic diagnosis ('PGD') research[81]) two days before egg collection. The authors state: 'Giving the research information 2 days prior to oocyte retrieval allowed time to ensure that both partners had *thoroughly considered the proposed research study and its implications* before consenting for research.'[82] In the light of comments made by many of the interviewees cited above and of our discussion particularly of information and voluntariness, we respectfully doubt that this would have been the case. The embryo donation rate, the issue of central concern to the authors, was 54.3%, which the authors note is 'higher than (10-21%) in most of the other reported studies'.[83] (Recall here that in Part 1 we observed that a participant from Site 2 told us that 98% of couples elect to freeze embryos when given the choice, although at that site the actual number of couples freezing was about 70–75%.) Of those who consented to donation at the Newcastle clinic, 94% did so on the day of egg collection and 6% on the day of embryo transfer.[84] Strikingly, none of the couples who consented asked any questions relating to stem-cell research,[85] which we suggest may be best explained by couples' focus on treatment at this time. Importantly, the study found that 'the number of follicles and embryos and previous failed fertilisation has a significant influence on a couple's decision to donate the spare embryos for research'.[86] In our view, this is unsurprising since these would be the key factors affecting a couple's prospects of success from IVF.

On the goals of research, the authors note that '[f]or isolation of an ES cell line from the inner cell mass, it is essential that these suboptimal surplus embryos develop to blastocyst stage' and further that a then-recent study suggested that *frozen* embryos were less likely to do this.[87] Most significantly, of the 'suboptimal surplus' embryos donated to research in this study, 34% did indeed develop into blastocysts. From the perspective of the donors, this is a highly significant

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[80] Ibid, 2092.
[81] PGD involves removing a single cell from a day 3 embryo and testing it for a serious genetic condition. 'Affected embryos' are those that have tested positive for a serious genetic condition. For further discussion, see eg R Scott and others, 'The Appropriate Extent of Preimplantation Genetic Diagnosis: Health Professionals' Views on the Requirement for a 'Significant Risk of a Serious Genetic Condition'' (2007) 15(3) Med L Rev 320.
[82] Choudhary and others, above, n 79, 2094, our emphasis.
[83] Ibid and references therein.
[84] Ibid, 2092.
[85] Ibid, 2093.
[86] Ibid, 2094.
[87] Ibid, 2095.

concern and it brings us to a crucial point that may be little known outside the clinic and the research laboratory, which is that a *good research embryo might also be a good treatment embryo*. In other words, 34% of the 'suboptimal' embryos in fact had good potential to result in a live birth.[88] For this reason, the fact that they were 'not required for treatment'—a categorisation they must have been implicitly given in order to comply with the HFEA *Code's* requirement that only such embryos can be used for research—can only be explained by the operation of the freezing policy, a point to which we return in the next section.

In our view, the critical point that an embryo that is *good for research* (especially stem-cell research since this requires, first, the formation of a blastocyst) *might also be good for treatment* is an additional highly important point about which a donor of a fresh embryo should be informed. Indeed, a number of our participants commented on the significant implications of this for consent and freezing issues. Embryologist 34 (Site 1) observed:

> [W]hen we say to patients . . . 'Oh well if your embryos are not good enough for your own use, then we can either, we'll either discard them, if they're only worth discarding, those embryos.' But then you say, 'Oh well we might use them for research,' but then embryos for research need to be good quality, and I think that's the *missing link* in some ways – is nobody says that . . . *nobody really sort of says about the fact that embryos for research are good quality embryos that potentially do have that, well that have that potential to make a pregnancy*. If then, if they're really poor quality, then they're not going to be of any use in research.[89]

S/he explains that this potential of embryos accounts for 'why we've gone over to keeping the embryos a bit longer, to give them every opportunity we can to show us that they . . . are continuing to develop and with good quality'. Here s/he is referring to the clinic's use of blastocyst culture, which was not available at the time of the Newcastle study referred to above.

Indeed, it is appropriate to acknowledge here that the use of blastocysts more ubiquitously in IVF treatment has developed relatively recently, concurrently with initial attempts to grow stem cells from human embryos (first in the world in 1998[90] and in the UK in

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[88] This does not imply that a live birth would *necessarily* have resulted, only that there would have been a good chance of this happening.

[89] Our emphasis.

[90] JA Thomson and others, 'Embryonic Stem Cell Lines Derived from Human Blastocysts' (1998) 282 Science 1145–7.

2003[91]), and largely in response to a move to reduce multiple pregnancies by means of SET without compromising pregnancy rates.[92] Many clinics are still wary of so doing, not only out of fear that introducing new technology might reduce their established success rates, but because of the additional laboratory time and techniques needed for blastocyst culture; there are also those concerned about possible adverse effects on the embryo of using extended culture.[93] In other words, the possible usefulness of the 'research-allocated embryo' in treatment might be said to have crept up on clinics to some degree, without any conscious thought that research consent policies also need to change for the reasons under discussion here. With regard to the appropriate balance between treatment and research and the possibility of a fresh embryo making a good stem-cell line, strikingly Research Manager 32 (Site 1) observed:

> If there is a fresh embryo that . . . you could make a stem cell line from, then you have to ask yourself why it's not being frozen for later years in the patient's treatment . . . And you say, 'Hang on a minute, that really is, you know, that should be for the patient's use, not for the stem cells.'

And Embryologist 7 (Site 3) observed: 'I'm sure there would never be a case where, if there were suitable embryos to freeze, that, you know, they would go to research. But I wonder in big research labs if they freeze less because they have more embryos to research. I don't know. That's, it is rather – and I hope people wouldn't be like that.'

2. Freezing Policies and Patient Choice

We now consider the way the information and voluntariness elements of a couple's consent to the donation of fresh embryos to research may be compromised, with particular reference to a clinic's freezing policy, and the place of patient choice in relation to that policy. Shortly we revisit, with reference to the legal elements of consent, the policies at the clinics we visited that we first discussed in Part 1. Before this, we introduce further data from an empirical study conducted by others. This study, the results of which were published by Erica Haimes and Ken Taylor, interviewed 44 couples who had been asked to donate embryos to

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[91] 'First Human Embryo Stem Cell Success' (2003) 221 Bionews. This was at King's College London using 'affected' PGD embryos.

[92] Personal communication, Professor Peter Braude, above, n 19. We discussed SET in Part 1 above. On the use of blastocysts in treatment and SET, see eg DK Gardner and others, 'Blastocyst Score Affects Implantation and Pregnancy Outcome: Towards a Single Blastocyst Transfer' (2000) 73/6 Fertil Steril 1155–8.

[93] Personal communication: Professor Peter Braude, ibid.

research at another UK clinic.[94] The authors state that 'the study builds on an earlier investigation in the same clinic which indicated broad patterns of donor characteristics'.[95] Their footnote reference here is to the Newcastle study that we discussed above.

At the time of these authors' research (in 2005–06), the (Newcastle) clinic had a dual quantity–quality criterion, described by the researchers as follows:

> [T]his clinic has a longstanding policy, which predates involvement with hESC research, of caution towards freezing embryos, due to concerns that it gives couples false hopes about future outcomes, given the likely deterioration on thawing, and also because of the expense of freezing. The clinic only freezes embryos if there are *four or more good* quality ones left after embryo transfer . . .[96]

In a further paper, they describe the policy slightly differently, referring to 'freezing a minimum of four *top* quality embryos'.[97] (Of course these were some of the concerns also expressed by those we interviewed at Site 3, which had a three-embryo freezing policy, as discussed in Part 1.) Although there is no reference in their papers to patients being permitted to override this policy, it seems unlikely that it admitted no exceptions and, as noted above, the Choudhary and others study referred to requests for freezing being 'considered'. That said, the empirical evidence in the Haimes and Taylor study suggests that many couples were in fact unaware of any options they may have had. Indeed, the researchers found that nearly all the couples interviewed would have preferred to transfer two embryos and freeze the rest; further, they were not clear about several aspects of their treatment, notably: how a judgment as to embryo quality had been made; how a decision about what to do with the remaining embryos had been reached; why they had not met the conditions of the freezing policy; and whether the clinic's involvement in research had any bearing on the decisions made.[98] At least fifteen couples said 'that they were not told much or anything at this stage and this had left them puzzled' and also that they did not know whether embryos not 'good enough' for clinical use were 'good enough' for research.[99] One

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[94] E Haimes and K Taylor, 'Fresh Embryo Donation for Human Embryonic Stem Cell (hESC) Research: the Experiences and Values of IVF Couples Asked to be Embryo Donors' (2009) 24 Human Reproduction 2142–2150.
[95] Ibid, 2142, footnote omitted, citing Choudhary and others, above, n 79.
[96] Haimes and Taylor, above, n 94, 2144, our emphasis.
[97] E. Haimes and K. Taylor, "The Contributions of Empirical Evidence to Socio-Ethical Debates on Fresh Embryo Donation for Human Embryonic Stem Cell Research", (2009) Bioethics 334–341, 336, n. 8. Our emphasis.
[98] Haimes and Taylor, above, n 94, 2144, 2147.
[99] Ibid, 2144.

couple was puzzled that after being told that the plan was to transfer two of fourteen embryos that had been created, the response to the question of whether there were any suitable for freezing was that there were apparently none. The woman adds: 'So I don't know whether that was below the four because I believe it's got *be four perfect ones*, then they'll go ahead and freeze them. . . . So maybe there were one or two perfect ones used for research that they couldn't use in the freezing process. I've no idea.'[100] Haimes and Taylor observe here that '[i]t is important to add that this person immediately said, "I understood at the time that things would happen that way and I understood fully" . . . . However, she is clearly indicating that there was *ambiguity in what was said or in how she understood it*'.[101] Although some couples were happy with the way embryos had been selected for transfer, others questioned the decision-making process. One woman observed 'they've probably thrown some good ones away, you don't know'.[102] This was a particular worry for couples with more than two top quality embryos left after transfer but less than four. Of those interviewed, more than eleven couples said they had at least one top quality embryo that had not been used in treatment or frozen.[103] Haimes and Taylor strikingly characterise the additional embryo(s) as 'the troubling third embryo', in relation to which one woman observed 'that might be my one chance of having a baby and I've given it away for this research'.[104] Notably, another woman said:

> [T]hat possibility had not occurred to me – that you'd have a viable embryo that they would not freeze. . . that wasn't covered particularly well and that's the bit afterwards I said to [partner] that I didn't feel happy with . . . I felt differently about donating the viable embryo . . . because *the way I felt it had been worded was, or how I understood it, was all the viable ones would be frozen* . . . The non-viable embryos that weren't suitable for freezing . . . I had no problems with, but . . . the viable embryo, yes I did. . . . I don't think I had really appreciated the emotional aspect of [long pause] . . . wasting my own eggs, if you see what I mean? That, *that* was a loss . . . [105]

Strikingly, Haimes and Taylor found that at least nine couples questioned (albeit typically 'hesitatingly' or 'apologetically') whether

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[100] Ibid, 2145, our emphasis.
[101] Ibid, our emphasis.
[102] Ibid, 2146.
[103] Ibid.
[104] Ibid.
[105] Ibid, first emphasis ours; second emphasis in original.

treatment was of secondary importance to the clinic, compared with research.[106] Although interviewees had been reassured about 'proper procedures', they still had doubts.[107] Not surprisingly, they found that the interviewees' priority was to have a child. One interviewee observed that although it would be 'wonderful' to cure Parkinson's, 'really our priority is just to have a baby'.[108] Haimes and Taylor note that '[s]everal said they were happy to donate to research as long as they had first selection of the embryos and only those not useable for their treatment went to research'. In their further paper, Haimes and Taylor observe that 'IVF is still an evolving field and elements of [the clinic's] policy have since changed'.[109]

Overall, from a legal perspective, there may be two significant problems with these practices, at least as these are reported in the Haimes and Taylor papers. First, as indicated in our discussion above, it is possible that there were inadequacies in the information processes in play. There is considerable evidence that on some occasions there was a lack of comprehension as to the reasons behind a decision not to freeze any embryos from a given treatment cycle and no awareness of any options (assuming these did exist) to override the freezing policy. Whether this stemmed from inadequate information is impossible to assess, given that this study focused on patients' views and experiences, but it is at least conceivable that this was the case (and in any event the HFEA's requirement for a 'check' on patients' understanding prior to consent to donation to research, discussed above, should be recalled). In such cases, the legal requirement that a couple should be appropriately informed in order to consent to an embryo being 'spare' and available for research would not always be satisfied. Second, in relation to any couple with between one and three good quality embryos left after initial embryo transfer, the policy and the way it was apparently explained in relation to the non-transferred embryos appears to have compromised the voluntariness of couples' consent to an embryo being categorised as 'spare', and subsequently their consent to its donation to research. This is in the sense that (at least as reported in these papers) many couples were not informed, or not sufficiently informed, that they may have had the option of overriding the policy (if this were the case) and thus freezing between one and three remaining viable (preferably good- or reasonable-quality) embryos. Alternatively, they *were* sufficiently informed but nevertheless felt unable to override the application of the policy in their case.

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[106] Ibid, 2147.
[107] Ibid.
[108] Ibid, 2144.
[109] Haimes and Taylor, above, n 97, 336, n 8.

We can see that a minimum-number policy (one with the twin criteria of quantity and quality) has the ability to limit the number of embryos that are recommended to continue to be available for treatment purposes. With reference to freezing policies generally, a couple's 'consent' to any given embryo being 'spare' may be compromised, and potentially rendered invalid, by flaws relating to information and/or voluntariness, which we now summarise with attention also to the material from our study.

Turning first to the information element, one question will be whether a couple is adequately informed of the reasons either for the *quantity* or the *quality* criterion or both. Do they have the right to such information? Since we have argued that the amended 1990 Act gives couples *some* control over their embryos' use in treatment, they should be informed of the rationale for any given freezing policy or recommendation (including the chance of embryos surviving the thaw, the success rates of the clinic with frozen replacement cycles, and the cost implications of different choices[110]) and of their options in relation to the application of that policy or recommendation, so that they are able to override it if they so choose. With regard to freezing policies and advice generally, Embryologist 34 (Site 1) observed: 'It shouldn't depend what unit you go to, your chances of having your embryos frozen.' We saw in Part 1 that Site 3 had a dual quantity and quality freezing policy, although we found ample evidence (reiterating here that this was from the viewpoint of the staff that we interviewed) that patients were informed of the rationale for the policy and their options in relation to its application to them. However, where a clinic has a quantity criterion about which a couple has *not* been adequately informed, they would be unable to make an informed assessment as to whether they wish to consent to the disuse of any given embryo in treatment on the basis that it is 'spare', so that this consent, and the consent to its donation to research that may follow, could be flawed.

Turning to voluntariness, even if a couple is sufficiently informed about the details of a clinic's freezing policy—particularly one with a dual quantity and quality criterion—and how it applies in their case, we need to consider how they stand in relation to it. Assuming the application of the policy amounts to a recommendation, one question might be whether patients are aware that they are entitled to override that recommendation and to elect to freeze fewer than the requisite number (under the policy) of remaining good- or reasonable-quality embryos and even embryos that are at least viable (though with fewer

[110] A number of PCTs fund the stimulation cycle but not the subsequent freezing (£250-850) nor the replacement cycle (£300-990). Personal communication: Professor Peter Braude, above, n 19.

chances of success with these). In the clinic we studied that had a dual quantity/quality policy (Site 3), there was evidence that the staff considered that this was a matter of patient choice (subject to funding issues) as we indeed concluded that it must be, by law, at the end of Part 1. Whether *patients* in that clinic were in fact typically aware that the choice was theirs would be an important question reflecting on the quality of the information processes at stake. Questions about patients' awareness of their choices could also be asked about the two clinics that had a 'quality only' freezing policy, although again we found considerable evidence of *staff's* awareness of and keenness to facilitate patient choice.

A second question regarding voluntariness would be how hard it actually is for patients to question and potentially override a given recommendation about freezing. We saw in Part 1 regarding the dual quantity/quality policy at Site 3 that one health professional referred to patients having to be quite 'assertive' and another to cases when patients 'insist'. The context of any discussions also needs to be borne in mind here. Patients undergoing assisted reproduction treatment will typically be under a lot of pressure (emotional, often financial, and physical for the woman) and may feel vulnerable.[111] There may also be feelings of indebtedness or gratitude to those assisting them and a wish to please them, as may occur generally with patients at the interface between treatment and research and notwithstanding the separation of treatment and research roles that is emphasised in the HFEA *Code*.[112] In turn, these factors may affect a couple's ability to question recommendations which, of course, there may generally be good reason to trust, as part of our discussion in Part 1 tried to show.

In short, if the information, voluntariness (or, more rarely, capacity) elements of the legal concept of consent are compromised for any of the reasons discussed in this Section B when patients supposedly 'consent' to certain embryos being 'spare' and passing out of clinical use to research, that consent may at the least be of poor quality. This is in the sense that there is a risk that the couple might have decided differently. It could also be invalid, with significant implications that we now spell out.

C. Flawed Consent to Research and Possible Effects on Treatment

First, an invalid consent would be in breach of the consent provisions under Schedule 3 of the HFE Act 1990 (as amended) compliance with

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[111] See also eg Holm, above, n 7.

[112] HFEA, above, n 6, eg R.27: 'The centre must establish, implement and comply with documented procedures to ensure that clinical and research roles are separated.'

which, it will be recalled, is a license condition under section 12(1). We have seen that the Act requires a couple's consent for various purposes including treatment and donation to research. The consent to an embryo's disuse in treatment would be invalid but so too, flowing from this, would be a couple's consent to the use of that embryo in research. As for the legal consequences, under section 18(2) of the amended 1990 Act, the HFEA 'may revoke a licence . . . if . . . (b) it is satisfied that the person responsible has failed to discharge . . . the duty under section 17'. A requirement under section 17(1)(e) is that 'the conditions of the licence are complied with'. It follows that there could also be significant breaches of the HFEA *Code's* provisions interpreting the Act. For instance, if a couple has supposedly 'consented' to the donation of an embryo to research in the face of a minimum-number freezing policy, when in fact they would have chosen to freeze it for future clinical use because it was an embryo of good or reasonable quality, then it is possible that an embryo with the potential to result in the birth of a child would have gone to research. Importantly, we have seen that an embryo that is useful for stem-cell research will be one that can form a blastocyst with an inner cell mass, exactly the kind with the potential to result in the birth of a child. In effect, then, and of considerable significance, an embryo will have gone to research that may in fact have been suitable for treatment and therefore 'required' for treatment purposes, thinking of the language in the HFEA *Code*. Recall 'that only fresh or frozen . . . embryos *not required for treatment* can be used for research'.[113] (We do not suggest that this has ever been intentional on a clinic's part.) In our view, a couple would believe that they *require* any embryo that could feasibly lead to a successful pregnancy and it is irrelevant to them whether that embryo is accompanied by the residual number a clinic considers appropriate to freeze (subject to any financial obstacles or other concerns). This is because freezing will increase their options for further treatment, should this be needed, so that they will then be able to choose between a frozen-replacement cycle or a further fresh one (as noted earlier, based on information regarding the chances of thawing, a clinic's success with frozen-replacement cycles, 'banking' and respective costs).

Moreover, and just as significantly, where one or more embryos goes to research that may in fact have been suitable for treatment this could breach the *Code's* provision 'that donating . . . embryos to research in the course of treatment services *will not affect the patient's treatment* in any way . . . '.[114] To be clear on this point, this is because an embryo with

[113] Ibid, above, n 6, para 22.7(h), our emphasis.
[114] Ibid, above, n 6, para 22.7(f), our emphasis.

live-birth potential will have been removed from clinical use. (Again, we do not suggest that this has ever been intentional.) It is likely that this could affect treatment outcomes—including by giving rise to the need for further fresh otherwise avoidable cycles, with all the burdens inherent therein—in at least some cases. As for the consequences of one or more breaches of the *Code*, the *Code* itself is of unclear legal status; although a breach is not an offence, it may be considered by a licence committee when deciding whether to vary or revoke a licence.[115]

A couple would have no action in respect of an invalid consent at common law, since consent to an embryo passing out of the clinic as 'spare' and over to the research laboratory does not involve a 'touching', required for an action in battery. As argued, however, consent to an embryo's disuse in treatment on the basis that it is 'spare' and so to its availability for research, has the potential to impact on further aspects of what we called the 'treatment process'. This is where additional fresh cycles become necessary because one or more embryos that could have been frozen and that a couple would have wished to freeze (assuming for example no financial constraints) were not frozen in a previous fresh cycle. In such a case, a woman who had not given birth to a child as a result of the first cycle or who in any event was trying to have another child, would be 'consenting' to an additional fresh cycle on the incorrect understanding that there were no embryos from the previous cycle of sufficient quality to freeze or because she understood that she did not have the option, or felt unable, to request this. Since the subsequent fresh cycle should have been avoidable even if only one embryo had been frozen (here she could also elect to 'bank' embryos), the voluntariness and information elements of her consent to it are also compromised. As for the legal consequences, further treatment will involve various touchings (blood tests, egg retrieval, embryo transfer) and so a battery action would at least be theoretically possible, but proof of such a claim would be hugely complex and fraught with difficulty.

III. ENHANCING THE QUALITY OF CONSENT AND PROTECTING REPRODUCTIVE OPTIONS

For the reasons identified above, seeking consent for the donation of *fresh* embryos to research may affect the quality and on occasion validity of consent, with various possible impacts on patients. Accordingly, couples should not be approached for consent to the donation of their embryos to research at least until they have decided not to undergo any further treatment, and *preferably* not until their frozen embryos

[115] Jackson, above, n 71, 766.

are coming to the end of their statutory storage term, at which point their reproductive wishes in relation to those embryos cannot change. Significantly, this is to recommend that *couples should not be approached for the donation of fresh embryos to research* (with a few exceptions that we discuss below). Although the ideal of 'fully informed consent' is most likely unattainable,[116] the information, voluntariness, and capacity elements of consent are likely to be satisfied as much as would ever be possible (an important caveat) at the point where no further treatment can be sought using those embryos (because of the expiry of the statutory storage term).[117] The point of this recommendation is to enhance the legal quality of various consents, to avoid some invalid consents, to avoid a possible impact on the treatment process, and to maximise a couple's treatment, and therefore reproductive, options since embryos are a distinctly *finite* resource for them. Research can proceed with frozen embryos (subject to some exceptions regarding fresh embryos noted below).

Our recommendation is echoed by elements of the scientific and clinical community in the UK. For instance, Stephenson and others—noting that the kind of embryo that is good for stem-cell research is the kind that may be good for pregnancy, and also the unpredictability of embryo development (so that an embryo that is assessed on day three as being of poor quality may in fact develop into a blastocyst on day five or six)—argue that 'it is ethically questionable whether the use of "surplus" embryos for stem cell derivation is in the best interests of the IVF patients trying to maximise their chances of pregnancy'.[118] Given the increasing use of blastocyst culture, they therefore suggest that 'the ethical source' of embryos for research will shift to 'frozen embryos or affected PGD embryos'.[119]

Our recommendation is also in accord with the American Society for Reproductive Medicine, whose Ethics Committee has recommended that '[t]he final decisions on the donation of embryos to ES cell or other research must occur after the patients' infertility needs are met or the patients discontinue therapy', reasoning:

> It is important that patients decide to donate embryos for research only after they have decided not to continue storing their embryos.

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[116] For recent discussion, see N Manson and O O'Neill, *Rethinking Informed Consent in Bioethics* (CUP, Cambridge 2007).

[117] Such embryos would be what Søren Holm has called 'finally spare', and in relation to which there would be no possibility of coercion. Above, n 7, 66.

[118] EL Stephenson, C Mason, and PR Braude, 'Preimplantation Genetic Diagnosis as a Source of Human Embryonic Stem Cells for Disease Research and Drug Discovery' (2008) BJOG 158–65, 159.

[119] Ibid.

> Making separate decisions about no longer using embryos and donating them for research guards against pressure being placed on patients to donate embryos. . . . Using only frozen embryos for research ensures that time passes between the creation of embryos for conception and their donation for research . . . Donation of fresh embryos . . . increases the chance that decisions will be made quickly and later regretted by patients.[120]

We draw attention here to the emphasis on separate decisions about not using embryos on the one hand and donating them on the other. Further, from an ethical viewpoint, Carolyn McLeod and Françoise Baylis have argued that donation of fresh embryos to research is against the interests of female IVF patients, and that 'autonomous' consent to such may be compromised by misunderstandings or coercion.[121]

There are a few *exceptions* to our recommendation. First, there may be embryos that are clearly not viable. (These will in fact be of no use in stem-cell research but may be of some use in other research, or in training embryologists.) Second, a couple may not wish to freeze embryos, for instance for religious reasons, or may be unable to do so for financial ones. Financial difficulties may, unfortunately, compromise voluntariness. In this case, if the couple prefers to give the embryos to research rather than let them perish, then donating to research may be of some value to them in these less than ideal circumstances. Third, embryos that have tested positive by PGD may be discarded unless used for research, although this may turn on whether there are other viable embryos from a treatment cycle, and also of course the couple's wishes. This is because the revised HFEA *Code*, with reference to the amended 1990 Act, stipulates only that such embryos 'must not be preferred'[122] at the point of transfer, that is, if 'there is at least one other embryo suitable for transfer that is not known to have the characteristics'.[123] (Whether couples could in fact elect to freeze these 'affected' embryos is unclear but in any event '[t]he use of an embryo known to have an abnormality . . . should be subject to consideration of the welfare of any resulting child and should normally have approval from a clinical ethics committee' (that is, with reference to section

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[120] American Society for Reproductive Medicine: Ethics Committee Report, 'Donating Spare Embryos for Stem Cell Research', (2009) 91/3 Fertil Steril, 667–670. The Committee expressed the same view in its earlier opinion in 2002.

[121] C McLeod and F Baylis, 'Donating Fresh Versus Frozen Embryos to Stem Cell Research: in Whose Interests?' (2007) 21/9 Bioethics 465–77.

[122] HFEA, above, n 6, T86 and T87.

[123] Ibid, 'Interpretation of Mandatory Requirements', Box 10C.

13(5) of the amended 1990 Act).[124]) However, a couple who has chosen PGD for a serious inheritable condition is unlikely to wish to have an 'affected' embryo transferred or frozen and is more likely to consent to such embryos passing out of treatment use as 'spare'. In all the cases noted here (subject to the caveat just discussed regarding 'affected' PGD embryos), it would be legitimate to request the donation of fresh embryos to research, including stem-cell research. The same would apply, for instance, to an embryo that was in some way the result of abnormal fertilisation.

Our recommendation and the exceptions are also in line with what we dub the 'ethical priority' in the use of embryos for research discussed by some of our research participants. Genetics Scientist 33 (Site 1) suggested that 'affected' PGD embryos were the most ethically unproblematic, followed by frozen and lastly fresh embryos, in relation to which s/he had significant concerns. This hierarchy was supported by a number of other participants. Embryologist 34 (Site 1) said fresh embryos should never be requested because an embryo that would be good for treatment might go to research. Stem-cell Scientist 35 (Site 1) reasoned:[125] '[W]e don't agree with the use of fresh non-PGD embryos . . . the *patients aren't here to give us research material, they're here to get pregnant* . . . they get all the embryos that have any possible chance of . . . pregnancy' and described requests for fresh embryos as 'a whole other can of worms which we avoid here.' Embryologist 7 (Site 3) observed that the 'ideal time is to use the frozen embryos when people have gone through their [treatment] . . . [*W]hen they're in a consultation . . . they're there to get pregnant and have treatment, they're not there to think about research*'.[126] Lastly on this point, Genetics Scientist 33 (Site 1) observed: 'So . . . that one would always remove the argument that you're actually taking for stem-cell research . . . embryos which could have been replaced . . . These ones are the frozen ones at the end of their storage time, aren't required any more.'

In recommending that fresh embryos should not be sought for research (subject to the exceptions discussed) we note that, although in the past live-birth rates using fresh rather than frozen embryos have been higher, that gap has now narrowed considerably, especially with blastocyst freezing and SET.[127] Further, since blastocyst culture is

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[124] Ibid, para 10.7.
[125] Our emphasis.
[126] Our emphasis.
[127] For recent evidence, see eg T El-Toukhy and others, 'Delayed Blastocyst Development Does Not Influence the Outcome of Frozen–thawed Transfer Cycles' (2011) 118 BJOG 1551–6. See also W Schoolcraft and others, 'Live Birth Outcome with Trophectoderm Biopsy, Blastocyst Vitrification, and Single-nucleotide Polymorphism Microarray-based Comprehensive

increasingly becoming the norm, and with it the freezing of blastocysts, the worry that freezing embryos may give 'false hope' to a couple will be reduced. Overall, as we have indicated, our recommendation is aimed at protecting reproductive interests by maximising treatment options. So, for example, if a woman does *not* give birth to a child as a result of her first cycle of IVF, she can then elect *either* to have a frozen replacement cycle, provided that embryos from the previous cycle have been frozen where possible, *or* to undergo the risks of another fresh cycle. Alternatively, if she *does* give birth to a child but later wishes to have another child, a minimum period of about fifteen months will ensue between her first and second cycles of IVF. During this time, her fertility will have declined—particularly if she is not young, as is often the case with IVF—so that she may respond less well to the stimulation drugs in a second fresh cycle. In this event, again it is preferable that she *also* has the option of using frozen embryos created in her first cycle if she wishes.

This protection of reproductive interests may come at the 'cost' of generating greater numbers of potentially difficult decisions that have to be made about the disposition of frozen embryos that are no longer needed, although the increasing practice of freezing blastocysts will in fact reduce the number of embryos that are frozen. (Of course, freezing also has financial costs, as noted earlier.) In this light, before consenting to freezing, patients should be advised of these possible difficulties.[128] Later on, when disposition decisions have to be made, the role of supportive counselling might be further explored and emphasised, as suggested elsewhere.[129] We do not have the scope further to discuss this here. We would emphasise, however, that along with advice as to the possible difficulties of making decisions about embryos that are not needed any more, couples should also be advised that freezing sufficiently good non-transferred embryos will help maximise their treatment options, and hence best protect their reproductive interests, over time.

Chromosome Screening in Infertile Patients' (2011) 96/3 Fertil Steril 638–40 (which also involved biopsy for chromosome testing).

[128] For discussion of couples' highly personal views about their embryos and how this contributes to the difficulties of making decisions about frozen embryos, see eg R Nachtigall and others, 'Parents' Conceptualization of their Frozen Embryos Complicates the Disposition Decision' (2005) 84/2 Fertil Steril 431–4. There is a significant body of literature on this issue.

[129] For discussion of ways to help people make decisions about frozen embryos, see eg G Fuscaldo and others, 'How to Facilitate Decisions about Surplus Embryos: Patients' Views' (2007) 22/12 Human Reproduction 3129–38; K Hug, 'Motivation to Donate or Not Donate Surplus Embryos for Stem-Cell Research: Literature Review' (2008) 89/2 Fertil Steril, 263–77, 274. On the question of what information should be given to couples before they freeze their embryos see S de Lacey, 'Patients' Attitudes to their Embryos and their Destiny: Social Conditioning?' (2007) 21 Best Pract Res Clin Obstet Gynaecol 101–12.

Finally, we support our recommendation with reference to a critique of recent case law and subsequent legislative developments. In *Evans v UK*,[130] embryos were created with the gametes of Ms Evans and Mr Johnson with a view to immediate freezing and subsequent use in assisted reproduction treatment following ovarian cancer treatment for Ms Evans. Mr Johnson subsequently withdrew his consent to the embryos' continued storage or use in treatment. In proceedings that went as far as the Grand Chamber of the European Court of Human Rights, Ms Evans unsuccessfully challenged the provisions of the (unamended) HFE Act 1990 that required such embryos to be allowed to perish once one gamete-provider withdraws his or her consent to continued storage or use.[131] While it remains the case that once one member of a couple has withdrawn consent for use or continued storage any given embryo must be allowed to perish, the amended HFE Act 1990 now specifies that, to allow time for reflection, there should be a 'cooling-off' period of one year between the time that one member of a couple withdraws consent to the continued storage or use of an embryo in treatment and the destruction of that embryo.[132] There is now, therefore, an explicit legal recognition (at least regarding the situation relevant to separating couples) that the option to use an embryo in treatment needs to be protected because of possible changes of mind. The finite nature of the resource that embryos are is implicit in this development. *Evans* is also of significance because it effectively highlights the importance of attending to the quality of the consent *actually* given in any case, as Sally Sheldon has argued.[133] Her analysis concerns the quality of consent to the creation of embryos for treatment purposes (which in *Evans* was given in highly charged emotional circumstances under pressure of time). However, by analogy, her critique affirms the importance of attending to the quality of actual consents in *general*. Such consents could encompass consent, in the first instance, to the disuse of an embryo in treatment on the basis that it is 'spare' and so, potentially, to its use in research, and consent to one or more possibly otherwise avoidable subsequent fresh treatment cycles. Our criticisms of the *U v Centre for Reproductive Medicine* case, in which the Court of Appeal arguably insufficiently attended to the quality of a withdrawal of consent, are also in point here.[134]

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[130] 46 EHRR 34.
[131] HFE Act 1990 (as amended), above, n 1, Sched 3, para 8(2).
[132] Ibid, Sched 3, para 4A(4)(a).
[133] S Sheldon, '*Evans v. Amicus Health Care*: Revealing Cracks in the "Twin Pillars"', (2004) 16 Child and Family Law Quarterly 437–52, 443.
[134] Above, n 59.

IV. CONCLUSIONS

In the course of our analysis of the process of consent to the donation of so-called 'spare' embryos to research, we have highlighted a fact that may be little known in the debate about embryo research: namely, that a good research embryo may well be a good treatment embryo, particularly with regard to stem-cell research. No-one who has had to resort to assisted reproduction treatment in order to start or add to a family would give away fresh embryos of this kind *by choice*.[135] In this light, it is unsurprising that having completed IVF treatment has been cited as one factor contributing to couples' willingness to donate embryos to research, along with having non-viable embryos.[136] We recommend that only frozen embryos that are, preferably, coming to the end of their statutory storage time should be sought for research (apart from the exceptions discussed).[137] This is intended to enhance the quality, and protect the validity, of what we have shown to be three related consent processes: consent to an embryo's disuse in treatment on the basis that it is 'spare' (as it must be for legal purposes, for instance, at the end of the statutory storage term); consent to its donation to research on this basis; and, similarly, consent to a further cycle or cycles of assisted reproduction treatment, should one or more be needed. (In the latter case, where for example no embryos could be frozen from a given cycle, a woman's consent to a further stimulation cycle would be on the correct understanding that the fresh cycle was indeed unavoidable.) At the same time, our recommendation aims to maximise the treatment, and therefore reproductive, options of couples needing assisted reproduction treatment.[138] In so doing, it recognises the finite

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[135] For evidence of this, see eg S Parry, '(Re)constructing Embryos in Stem Cell Research: Exploring the Meaning of Embryos for People involved in Fertility Treatments' (2006) 62/10 Social Science and Medicine 2349–59.

[136] See especially K Hug, above, n 129, 275, who also lists other factors. See also Parry, above, n 135, for further UK evidence that 'only when classified as unsuitable for reproductive treatments did participants consider their use in medical research as potentially legitimate' (at 2353).

[137] (Of course, as noted earlier, couples can choose a storage term of less than the statutory maximum, and can then elect to extend the term if they wish.) We acknowledge Haimes' and Taylor's interesting alternative suggestion that couples should not be approached for donation to research in their *first* cycle of IVF because (amongst other reasons) in subsequent cycles they 'would be better informed by experience and reflection, as well as by documentation, about the possible uses of their embryos, whatever the quality'. Haimes and Taylor, above n 97, 340; see also above n 94, 2149. However, for all the reasons argued here, we frame our recommendation more strongly. In the course of our argument, we believe we have addressed (to the extent that space has allowed) their various reasons for rejecting McLeod's and Baylis's suggestion that the donation of fresh embryos to research is not in patients' interests. McLeod and Baylis, above n 121.

[138] Of course, single women may also undergo treatment using donated sperm.

resource that embryos are for any given couple. This protection of reproductive interests is appropriate since those embryos that pass to the research laboratory from the clinic do so as a result of the cycles of treatment that couples undergo to try to have children.