

A challenged choice: donating spare embryos to stem cell research in Switzerland

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Summary

Research questions: Couples undergoing IVF in Switzerland may have embryos in excess of their clinical need that they can donate to human embryonic stem cell research. Thus a new practice has emerged in Switzerland when IVF treatment and embryonic stem cell research come into contact. This interface needs to be investigated from an ethical-legal point of view to facilitate a fair informed choice process for the couples involved.

Methods: Ethical analysis, patient perspectives elaboration. Interdisciplinary approach that draws on the research project JESP-ELSI (joint embryonic stem cell research project – ethical legal and societal implications).

Results and conclusions: To facilitate the donation of surplus embryos to human embryonic stem cell research, we propose a procedure of informed choice that fits to the current Swiss legal situation. In addition we identify problems within the current legal setting and suggest methods to improve communication at the interface between IVF and embryonic stem cell research from an ethical perspective.

Key words: *bioethics; patient perspective; embryo donation; informed consent; hESC research; Switzerland*

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The study was called JESP-ELSI (Joint Embryonic Stem Cell Project – Ethical, Legal and Social Implications). The scientific part, JESP, was initiated by Wolfgang Holzgreve (Basel) and Marisa Jaconi (Geneva). The ELSI part was headed by Christoph Rehmann-Sutter (Basel). All the authors were involved in JESP-ELSI, and in this paper we draw on our research throughout the interdisciplinary project.

Introduction

In Switzerland, the practice of conducting human embryonic stem cell (hESC) research with donated surplus embryos from in vitro fertilization (IVF) clinics began in 2005 within the legal framework of a new Stem Cell Research Act [1]. Initial practical experience with this framework can now be examined in an accompanying study of the ethical, legal and social implications of the law¹. This is still a novel process for all involved parties: the stem cell researchers, the IVF specialists, the obstetrical care teams and, of course, the couples undergoing IVF, who might be asked to donate a surplus embryo to hESC research. They are all confronted with a variety of ethical issues and legal challenges, some of them already known from other contexts, but others without precedents. Thus “embryo donation” is a new social function that has only emerged within the setting of assisted reproduction at the interface of IVF treatment and hESC research [2].

The practical interrelations at the IVF-hESC interface (between the therapeutic context of reproductive medicine and the sourcing of embryos for stem cell research) have produced a zone of

potential conflicts of interest around the production and fate of embryos [3]. Some authors argue against the donation of fresh embryos at all [4] on the grounds that, if the treating physicians have an interest in producing surplus embryos for stem cell laboratories, they cannot be described as working exclusively in the best interest of their patients, who want to use the embryos for pregnancy [5]. The legislator was aware of this potential conflict of interest when Art. 6 of the Stem Cell Research Act were drafted. This article already requires a strict separation between persons involved in the assisted reproduction procedure and those involved in the derivation of stem cells. In general, the Swiss Stem Cell Research Act was drafted within a discursive climate of embryo protection and includes safeguards to prevent the intentional production of a spare embryo [2, 6]. However, less attention was given to the situation experienced by the couples [7, 10]. In our study, we focused on the experience and the perspective of IVF couples having one or several spare embryos that could be donated to hESC research. Our research combined qualitative, legal and eth-

ical approaches. Elsewhere we have reported on the moral perception of the embryo by patients undergoing IVF, comparing Switzerland and the UK [10]. One part of our research was aimed at helping to establish an appropriate informed choice procedure for donation of spare embryos to hESC research. This required an international comparison of informed consent procedures [9]. A major part of our work, however, involved identifying legal issues that emerged in practice at the rapidly developing IVF-hESC interface in the Swiss context [8]. The present paper focuses on the requirements of a sound informed choice procedure within the given legal setting.

Since the Federal Stem Cell Research Act came into force in 2005, hESC research has been explicitly regulated in Switzerland. Under certain strictly defined conditions it is permissible to use 'surplus embryos' from IVF treatments to derive human stem cell lines. Embryos become surplus (or spare, supernumerary) in the sense of the law if they cannot be transferred to the woman's uterus in IVF treatment, for reasons of embryo morphology (poor quality embryos), or because of medical or other considerations which are *independent* of the aims of hESC research [11]. However, such surplus embryos are rare. The Federal Act on Reproductive Medicine – concretising Art 119. of the Swiss constitution – restricts the number of embryos developed in vitro to three per IVF cycle, and in principle all must be transferred to the uterus. Thus the occurrence of a surplus embryo is the exception rather than the rule within the regime of IVF treatment in Switzerland. Researchers conducting hESC research also need to prove that the research goals are valuable, and must apply for a licence for hESC derivation from the Swiss Federal Office of Public Health. This level of oversight aims to ensure that no human embryos are wasted.

Feki et al. [12] used surplus embryos that had been cryopreserved prior to 2001. Before the Federal Act on Reproductive Medicine came into force in Switzerland in 2001, cryopreservation of embryos was allowed. Under certain conditions, stem cell researchers may use these surplus embryos cryopreserved *prior to* 2001 for research purposes. Embryos that are spare in the sense of the current law may not be cryopreserved, but neither can they be used for deriving stem cells after their seventh day of development (Art. 17 para 3 Federal Act on Reproductive Medicine, Art. 3 para 2 lit. c Federal Stem Cell Research Act). Therefore, the decision time available to a couple who know they have a surplus embryo is very short. Our results from qualitative interviews with couples, who were asked to donate these *cryopreserved* surplus embryos to hESC research [10],

show that the period of time between IVF (and freezing) and the actual request is a significant factor in their situation. These former IVF patients know whether their IVF was ultimately successful, information that cannot be known by patients in a current IVF cycle who are asked to donate 'fresh' embryos. The experience of former IVF patients who receive a request for donation from their IVF clinics long after their treatment is completed, is therefore not directly comparable to that of patients who are asked within ongoing IVF cycles to donate fresh surplus embryos.

The patient point of view – Couples at the interface between IVF and hESC research

In the current Swiss legal setting, IVF doctors must inform the couples about the possibility of being asked to donate a surplus embryo to stem cell research, if this option arises concretely within an ongoing IVF cycle. But timing is critical. When such surplus embryos originate in ongoing IVF cycles, they are referred to as "fresh" surplus embryos. They can either be donated for hESC research or couples may decide to have them destroyed. A third option does not exist due to current Swiss prohibitions on cryopreservation of embryos and on donation for any purpose other than stem cell research. From an ethical point of view, the management of this process is not easy.

The ethical-legal issues of the choices available to patients at the IVF-hESC interface are under discussion in many countries [13]. Some of the international discussion focuses on comparing the policy approaches to hESC research [14], while a vast bioethical literature focuses on the moral status of the embryo in general [15–18]. The international debate agrees on one crucial point: within the options that are possible legally and biologically, the responsibility for deciding what will happen to their spare embryos rests with the couple.

From this point of view, some major ethical questions arise. Can couples decide to give surplus embryos to research while at the same time still trying to achieve pregnancy? How can this decision be best supported within an ethically sound process of informed choice? Can couples really understand their own role at the interface between IVF treatment and research? Is there a risk that they might be (or perceive themselves to be) exploited by giving away some of the 'precious' entities (the surplus embryo) that might in other circumstances have resulted in babies to research? These questions are not purely ethical ones, because the answers must be implemented within the existing legal settings.

Approaching the process of informed choice to donate surplus embryos

The role of the couple in the donation process

From a sociological point of view, a new *role* has been created in this interface: the “embryo donor” [2]. This new social role comes with new practical possibilities and moral responsibilities and influences the ‘identity’ (or the self-image) of patients in reproductive medicine. Symbolically and legally, this is expressed in the organization and performance of an informed consent procedure. As the word ‘consent’ presupposes acceptance we find it more appropriate to speak of an ‘informed choice process’ to indicate that the couple has the possibility of deciding the fate of their surplus embryos. Couples need to understand the choice with which they are confronted, and that they should freely decide either for donation, if they wish to have their surplus embryos used in hESC research or for destruction of the embryo if they do not.

Two additional questions arise at the very outset of the process: Do couples consider the practice that they are asked to decide on as a ‘donation’ ie as a gift, or as a ‘giving away’ of the embryo? And is the establishment of stem cell lines seen as just another way of ‘destroying’ their embryo? The patients’ understanding of the practice is likely to be significantly different according to whether they think: “I *gave away* my surplus embryo to research”, “I *donated* my surplus embryo to research”, or “My embryo was *destroyed and used* for research”. The language used may change the context, trigger certain decisions or favour one choice over another. For example, ‘donation’ is generally considered to be a good thing to do. There are analogies to blood, tissue, organ, sperm or egg donation. However, embryo donation cannot easily be compared with such other forms of donation, because the embryo with its potential for development is a unique entity and not comparable with other body parts that lack such a potential. Both IVF doctors and stem cell researchers need to take this into account.

As far as we can judge, no coherent linguistic practice has yet been established in this area. However, promoting the exclusive use of scientific language (zygote, blastomere, blastocyst etc.) would hardly be a solution. The ontological and moral status is an issue when it comes to decide upon the research use of an embryo that once carried the hopes of the couple for children. A seemingly neutral objective scientific vocabulary is ontologically not neutral, because it suggests that those entities are nothing but cells developing. Scientific language, in this context, is therefore not morally neutral.

Understanding the current legal setting

A key point of contention lies in the precise interpretation of what the law permits in terms of *in-*

forming patients and *requesting consent* to donate. Article 5 para 1 of the Stem Cell Research Act determines that a surplus embryo ‘may only be used for the derivation of embryonic stem cells if written consent has been freely given by the couple concerned’. Before such consent is given, the couple is to be provided with adequate information, verbally and in writing, in a comprehensible form, concerning the use of the embryo. Para 2 then holds that a “request [for donation] may only be made to the couple after the determination of the surplus status of the embryo.” The Ordinance on Stem Cell Research, moreover, stipulates in Article 2 para 4 that the couple must be given enough time to take their decision. However, Art. 17 para 2 of the Federal Act on Reproductive Medicine limits this time indirectly, when it states that an embryo *in vitro* can only be developed to the stage at which nidation (implantation into the uterine lining) would occur *in vivo*. Cryopreservation of the surplus embryo at this stage is forbidden.

Thus a complex grid of regulations results in a very narrow timeframe during which the couple must: (i) be informed that an embryo has become surplus, and why; (ii) be informed about the alternatives of donating this embryo to stem cell research or of having it destroyed (or allowed to die); (iii) undertake their considerations; and finally (iv) take a decision about the surplus embryo. One possible interpretation of the law is that patients may not be told about the possibility that a surplus embryo will arise until it does so, and if so steps (i) to (iv) might be difficult to complete in the short time of one to two days that is effectively produced by the combination of biology and the law.

However, the legislator is likely to have been aware of these constraints and another interpretation is more evident. The official commentary to the draft of the Stem Cell Research Act explains the regulation of the time point at which the request can be made (Art. 5 para 2, see above). According to the commentary this provision states that no *request* for donation should be made during the IVF procedure, at least until it is clear that an embryo has become surplus, in order not to influence the process of IVF [19]. The Ordinance on Stem Cell Research substantiating the Act on Stem Cell Research reinforces this timing in Article 1, when it requires the doctor to inform the couple that an embryo *has become* surplus, together with the reasons why and the consequences [20]. The commentary to the Ordinance states that the timing of the request is important in order to ensure the separation between IVF treatment and research. The couple should never find themselves in a situation in which they would have to decide between the use of an embryo for reproductive purposes on the one hand or for research purposes on the other [21].

However, the surplus embryo may also be considered as a 'side-effect' of IVF and the couple must be informed about all the potential risks of IVF before they can give their informed consent to this treatment. One risk is that an embryo, for one reason or another, cannot be transferred. It is imaginable that a couple might reject IVF treatment because they do not want to find themselves in a situation in which they would have to take a decision about a surplus embryo. Our conclusion is therefore that the law may be interpreted such that (i) couples should at least be informed about the possible *need for a future decision* in those exceptional cases when a surplus embryo is produced by their treatment, but that (ii) there is no room within the law for systematically informing the couple about the concrete *possibilities* of donation to stem cell research. This option can only be explained later when a surplus embryo has actually been produced. From the viewpoint of the current law, the concrete *request* to use a surplus embryo for hESC research cannot be made before it is clinically clear that the embryo is surplus.

The ethical complexity of informed choice

We have also drawn up an international comparison of guidelines for embryo donation to hESC research. The comparison was carried out to identify the most important elements that should be taken into account in developing an ethically sound informed choice procedure.

Thus we have analysed and compared 39 documents developed by governmental bodies, national bioethics committees, ad hoc advisory groups and national institutes of research in various countries that allow procurement of hESC from surplus embryos. Other documents by international organisations dealing with ethical issues of hESC research have also been considered. While keeping in mind that different national legal settings allow variations in the conduct of the informed choice process, a comparison of these documents has allowed us to identify a framework of three key elements for an ethically sound informed choice for embryo donation to stem cell research [9]: who, what and when.

(1) "Who?" – an informed choice procedure must specify who should give consent and who should obtain consent. (2) "What?" – it must also define what kind and amount of information should be provided to donors. (3) "When?" – it must be clear about the point at which informed consent (or non-consent) should be obtained and define the proper time schedule for the overall informed choice procedure.

The relevance of these three elements is substantiated by the literature on the ethics of embryo donation to stem cell research, in particular by Lo et al. [22].

In terms of the "who" element, all the documents investigated emphasise that couples should be asked for *specific* and *explicit* consent. The most important reason for this is that couples undergo-

ing IVF should be empowered to make voluntary and informed decisions about the use of their reproductive materials for research. This is a very different use for these materials than the one that couples envisaged when they decided to enter infertility treatment and raises new issues, including privacy and confidentiality of personal information, which must be addressed in an ethically acceptable manner. Most of the documents investigated also specify who should *obtain* consent. Some suggest that this should not be the treating infertility specialist, nor a member of the research team. The rationale is to avoid any possible influence (eg from fear or gratitude) on potential donors, and to ensure that their consent is truly voluntary. Within the current Swiss legal framework, however, it is the treating IVF physician who is supposed to perform the consent procedure (see 2.2).

The second element arising from the comparison of documents is "what" the nature of the information to be provided to donors should be. Although some documents are more precise than others in detailing information that should be given in order for the couple to make a decision, there seems to be general agreement on several items. Donors should be informed, (i) that the process of deriving hESC effects the 'destruction' of embryos, (ii) that they themselves will not benefit from the commercial potential of research outcomes, (iii) about the specific purposes of the research protocol or, where the donation is not limited to specific research purposes, the different possible categories of research use, so they can select those they find acceptable. The information provided to donors should (iv) allow them to understand the implications of research techniques that might raise special moral concerns, such as the production of stem cell lines or the use of somatic cell nuclear transfer. Potential donors should be assured that (v) embryos donated to research will not be used to create a pregnancy, (vi) their confidentiality will be protected by specific procedures, (vii) that their decision to give or to refuse consent will not affect the quality of IVF treatment they receive, and (viii) that they can withdraw consent, without giving reasons, up until the point at which the embryos are actually used in the research study.

Although several documents consider the careful timing of the informed choice procedure to be paramount, there is no general agreement on what information to provide, at what point and when consent should be obtained. Some documents recommend that donors should declare their willingness to donate or not before starting IVF. Others advocate a two-phase process: A preliminary decision should be made prior to the collection of gametes for reproductive purposes and donors should be asked for a final confirmation of this if and when surplus embryos remain after IVF treatment is completed. With regard to the timing of information provision, some docu-

ments suggest that potential donors should be approached as early as possible, even before starting

the infertility treatment, in order to give couples adequate time to make their decision.

Developing a fair informed choice procedure in Switzerland

Taking all these considerations and limitations into account, we propose the following elements for an appropriate informed choice process within the current Swiss legal situation.

Informed choice about donating surplus embryos

- **Who:** In Switzerland, it is the IVF doctor who informs the couple that IVF has produced a surplus embryo. If there is a surplus embryo, the doctor needs to explain why the embryo has become surplus and what options are available. If the couple decides against donation to hESC research, the surplus embryo cannot be stored or donated to other couples but will be allowed to 'die'. If the couples are interested in the possibility of donating the surplus embryo to hESC research, then the doctor moves on to provide further explanation of what they are consenting to. We propose that the international standard, that aims to avoid conflicts of interest and provide transparency about the intentions of the treating doctor and the stem cell scientists, would be ethically preferable here. That is, the Swiss informed choice procedure would be improved by removing from the treating physician the responsibility of approaching the couple and obtaining consent to donate.
- **What:** Couples need to be informed explicitly that there is no obligation to give their surplus embryo to research and that a refusal to donate to research does not have any effect on their ongoing IVF treatment. They must also be told that their personal data will be kept confidential. They must understand that they cannot receive financial compensation for their donation and that they will not have any rights to commercial gain from future stem cell lines. Couples also need to understand the link between their treatment and research ie they need information about the research project: Detailed information sheets about the research and the research team should be provided to them by the doctor. They should be able to contact the research team if they wish. They need to know that the embryo will be destroyed in the course of hESC research, that stem cell lines produced from the embryo may live on for a long time and be shared between laboratories, that hESC research is not the same as research to improve IVF techniques and that they can withdraw their consent for donation at any time before the embryos are actually used in the research study.

- **When:** In the interpretation of the current Swiss legal situation described previously, the whole process of information and consent has to be performed within the very narrow time span between the embryo being identified as surplus and the legal limit of its use in hESC research (up to six days after cell fusion). Thus the whole process of informing, reflection, discussion and informed consent is exposed to extreme time pressure. We suggest that the "when" element of the procedure of informed choice should be reconsidered and clarified when the current Swiss regulation is revised. We consider that the existing procedure in Switzerland may be interpreted so as to leave an unacceptably brief time between the provision of information to donors and the signing (or not signing) of the informed consent form. The provision that *information* about research donation may only be given after the embryos have clearly become surplus in the sense of the law, poses one of the biggest challenges to maintaining an ethically sound informed choice procedure within the current Swiss situation.

Points to consider in a future revision of the Swiss Stem Cell Research Act

1. Avoiding time pressure for the couples

Hence in our view there is one main obstacle that needs to be removed in the Swiss version of the IVF-stem cell interface. As we have noted, current legislation may be interpreted in a way that forces couples who may want to donate a surplus embryo for research to act under considerable time pressure. This might in turn hamper their understanding of the issues they are asked to consider, lower their capability to understand all the relevant aspects of the decision, and/or make it harder for them to consider the implications of their decision. A perfectly defensible alternative, and one which would be preferable in our view, is to provide *general* information about the *possibility* of donating any surplus embryo *before* the IVF treatment starts. Then the couple could think over this eventuality and be prepared for it should it actually occur. It is not clear that both partners will have the same initial opinion about the options. To discuss it between themselves, and possibly also with friends or relatives if they wish, requires time. Specific details of the research project for which the embryonic cells might be used, however, need not be given at this stage of decision making and the result of the decision does not need to be disclosed to the IVF doc-

tor. It is difficult to see how the couple's considerations of this question could unduly influence the IVF process if the IVF team does not know the attitude of the couple.

2. Transparent interface

A revision of the Stem Cell Research Act should also pay more attention to differences in the perspectives and goals of IVF treatment and stem cell research. Not only should the IVF treatment team not have a vested interest in producing extra embryos for their own in-house stem cell laboratory but patients also need to understand

the special role of their treating physician and not conflate it with the role of the stem cell researchers. If the treating physician is also the (only) person in charge of the informed choice procedure for hESC research, the patients' perception of this distinction will be blurred. In IVF centres it is possible to charge another person outside the treatment team eg a research nurse or a doctor who is not the treating physician, with the task of talking to the patients about the implications of research donation. In some centres it would also be possible for the patients to meet one of the stem cell researchers in person.

Conclusion

Although one aim of the Swiss Stem Cell Research Act was to avoid the exploitation of couples undergoing IVF as producers of embryos for stem cell research, its key concern was to protect embryos from being produced in excess and used for hESC research instead of being exclusively produced for pregnancy. The law defines a window that is narrow enough to avert both of these risks but still wide enough to allow the use of surplus embryos, in unavoidable but exceptional circumstances, in hESC research. These concerns were widely discussed at the time of drafting the legislation [6]. However, actual experience of putting the law into practice has revealed additional concerns, to some of which we have drawn attention in this paper, that were not predicted and therefore perhaps not taken adequately into account.

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