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Analysis of the medical, legal and ethical implications of the preparation of embryonic stem cells from surplus embryos – an empiric data assessment in four IVF-centres in Germany and Austria

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Despite the heated debate on the ethical acceptability of embryonic stem cell (ESC) research and the moral status of embryos before nidation, there is little understanding both of the procedure of in vitro fertilisation (IVF), during which the occasional supernumerary embryos are inevitably generated, and of the beliefs of patients undergoing IVF about the use of embryos for stem cell research. Thus it is of utmost importance to comprehend the precise steps involved in IVF and why supernumerary embryos are generated, as well as to know the beliefs of the patients about ESC research and the possibilities of generating ESC lines from the supernumerary embryos should they arise. A better understanding of the reasoning and frames of reference of the patients and their partners are fundamentals for an informed consent. The purpose of this study was therefore to analyse through structured interviews the relevant selection steps involved in the process of IVF, followed by a discussion about the ethical, legal and biological consequences on the one hand, and how patients reflect on the use of supernumerary embryos for stem cell research on the other.

Between September 2008 and September 2009, four IVF centres in Germany and Austria have been visited. For better outcome of IVF treatment, all four centres applied various technical measures at different steps to select the eggs and sperm cells, mostly by microscopic, morphologic criteria. One key difference in the 4 centres was sperm selection. Sperm selection was done only in one of the four visited IVF centres (Bregenz). For IMSI (Intracytoplasmic Morphologically Selected Sperm Injection), the shape, vacuole numbers and mobility of the sperm cells were examined under a high magnification microscope and subsequently introduced to the corresponding egg cells. Thus a selection was performed in all centres. The difference lies in when and how many selection steps were performed in the whole IVF procedure, i.e. selection of sperm cells used, selection of egg cells, and selection of fertilized eggs (embryos) on day 2 or on day 5 after ex-vitro cultivation. Another major difference among the four centres is the number of embryos selected for culture and the

duration of ex-vivo culture. According to the German Embryo Protection Act (Embryonenschutzgesetz) it is not permitted to (a) fertilize more egg cells than those that can be implanted within one cycle, (b) fertilize more than three egg cells within one cycle, (c) implant more than three embryos within one cycle. In all the centres more than three egg cells were usually harvested and fertilized initially as the success rate for IVF could be as low as 25-30%.

The second part of this project was to estimate how patients who underwent IVF treatment reflect on donation of supernumerary fertilized eggs/ embryos for stem cell research. How is their readiness to donate in the hypothetical scenario that they would have fertilized eggs/ embryos in storage which they would no longer need nor desire for fertility treatment? Our investigation showed that 44,5% of 157 couples who have responded to our questionnaire have declared their readiness to donate the supernumerary fertilized eggs for research purposes, whereas 30% were reluctant to donate their supernumerary fertilized eggs or embryos and 25,5% were undecided. This is consistent with the results described in the literature.

As a result of all of the collected data and the arguments in the literature, it seems worthwhile to clarify the legal status of the embryo and the procedure of IVF in Germany. A new balance that will take the enormous advances in biomedical, ethical, legal and social sciences into consideration should be sought to meet the needs of present day society. A possible solution might be to enact a so-called "Reproduktionsgesetz" that could comprehensively address all points at issue. In order to take the continuous innovations in this field into consideration, a regular revision of this law seems recommendable.