DESIGNER BABIES. A QUESTION OF ETHICS

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INTRODUCTION

One of the most interesting biomedical advances brought about by new technologies in recent years, and with undoubtedly the greatest social repercussion, is preimplantation genetic screening[1]. This technique has two fundamental applications: to produce babies free of a hereditary or genetic disease that their parents may have[2,3] and the production of designer babies[4].

The term “designer babies” may be used to refer to a range of reproductive techniques including the use of sex selection techniques to prevent the birth of children with x-linked diseases, preimplantation genetic diagnosis to select for embryos free from genetic disorders, selection techniques for eggs, sperm or embryo donors with particular characteristics, and the enhancement of features such as intelligence, sporting ability or attractiveness.

However, when discussing designer babies in this article, we will refer to a brother or sister produced by in-vitro fertilisation, capable of donating live-saving tissue to an existing child.

The production and subsequent use of designer babies has provoked widespread social debate, since trying to find a means to cure those sick siblings is something which is not only accepted, but also desired by a large part of society.

However, the production of designer babies entails specific medical[5] and ethical[6] problems. In this article, we will essentially address the latter.

At the start of this reflection, I believe it is necessary to point out that for the parents of a sick child, producing a designer baby i.e. a healthy sibling from whom the hematopoietic tissue required to treat the sick child can be extracted, is a longing desire which, from here forward, regardless of our subsequent considerations, we award all the respect it deserves.

Before proceeding to study everything related to designer babies specifically, particularly the bioethical aspects, I believe it is necessary to state that, given that assisted reproductive technology is necessary to obtain them, their production has, in addition to other ethical difficulties, all the moral difficulties that this technique entails[7].

Brief historical summary

The first cases in which preimplantation genetic diagnosis was considered for producing designer babies arose in the United States[4], Australia[8] and England[9]. This possibility led the media in those countries to dedicate a lot of attention to the matter and thus thrust something into the public gaze that until then had been relegated to the privacy of specialised laboratories.

The first designer baby was Adam Nash, produced by a team from the Reproductive Genetics Institute in Chicago, led by Yuri Verlinski[4]. Adam was created to obtain his hematopoietic tissue,

which was necessary to treat Molly, his six-year-old sister, who suffered from Fanconi anaemia. After four failed attempts[10], Adam was finally born on 29 August 2000 and the blood from his umbilical cord was able to be transplanted by Dr. John Wagner's team[11] to his sister in the first week of October that year, in the University Hospital, Minneapolis, Minnesota.

Clinically, it could be confirmed that Molly's blood cells had improved significantly three weeks after the transplant[11], which undoubtedly indicated that her bone marrow was recovering its functionality. Three years later her haematopoietic and immune systems were reported normal[12].

In 2002, also in the United States, the production of a second designer baby was also authorised; this time it was for an English couple who had moved to North America as this medical practice was prohibited in England at that time. The sick child suffered from β-thalassaemia major[13].

In 2001, in England, three families, the Hashmis, Whitakers and Fletchers, expressed their desire to have a designer baby[10].

The Hashmis had a son, Zain, who had β-thalassaemia major[14]. After a series of legal changes[15,16], in May 2003 the country's Court of Appeal authorised the production of the designer baby. The embryo produced by in-vitro fertilisation was transferred to Mrs. Hashmi, but unfortunately she miscarried in December 2003[10]. After trying six cycles of in-vitro fertilisation treatment, the Hashmis decided to abandon any further attempts[17].

The second English family, the Whitakers, who had a three-year old child who suffered from Diamond-Blackfan anaemia could not obtain

authorisation to produce their designer baby, so in October 2002 they travelled to Chicago, to the clinic where Adam Nash had been generated, with the intention of obtaining their designer baby, which they achieved in June 2004. The sick child had the transplant in July of the same year[10].

The third English family, the Fletchers, requested that the Human Fertilisation and Embryology Authority (HFEA) approve preimplantation genetic screening of in-vitro fertilisation embryos for treatment of their 2-year-old son, whose condition was the same as in the Whitaker case. In September 2004, the HFEA approved a licence for the Fletchers to undertake treatment in the United Kingdom[10].

In Sweden, in 2004, the Swedish National Council of Medical Ethics authorised the production of designer babies, but stated that the method should only be acceptable in cases when it could save lives that could not otherwise be saved[18]. This decision was not set into motion until July 2006[19]. In 2007 the first case was authorised, selected from four applications that had reached the health authority. It concerned a four-year-old boy called Felix. The boy's disease was adrenoleukodystrophy, a rare metabolic disease that causes damage to the myelin sheath of nerve cells[18]. On 28 May 2007, the National Board of Health and Welfare announced that it had authorised the other three cases[18]. Thus, Sweden became one of four countries that allow the production of designer babies. The others are Belgium, the United Kingdom and the United States.

In Spain, the first designer baby was born in Tenerife in 2005, although she was produced in the Chicago Reproductive Genetics Unit in 2004. The umbilical cord blood was used to treat her 14-year

old sister who suffered from β-thalassaemia major[20]. Also in Spain, in 2006, the relevant health authority was presented with 24 clinical protocols requesting authorisation to produce a designer baby; eight were selected from these and three were authorised, two children with β-thalassaemia major and the other with Fanconi anaemia[21]. After repeated attempts, they were unable to produce a useful designer baby in any of the cases[22]. The first one achieved in Spain, Javier, was born in Seville in 2008; he had been produced with the intention of being able to treat his brother who had β-thalassaemia major[23, 24].

Technique

Assisted reproductive technology is used to produce designer babies. From the parents' gametes, ovum and sperm, an indeterminate number of embryos are generated, usually not less than eight. Using preimplantation genetic screening[1], an embryo that does not have its sibling's disease and which is also histopathologically compatible with them is selected. This embryo is transferred to its mother, to achieve the respective pregnancy, which as we will discuss later, is often not achieved, and the rest of the embryos are discarded.

Medical indications

Designer babies are fundamentally used to extract their haematopoietic umbilical cord tissue which, in principle, may be useful to treat other children with neoplastic or non-neoplastic

diseases (Table 1)[25] or hereditary or congenital diseases (Table 2)[25], although in most cases it has been used to treat children with Fanconi anaemia or β-thalassaemia major.

Limitations of use

When the media refer to designer babies, they generally only do so to praise the goodness of this practice, which in itself has certain limitations. Possibly the most important is the time required to produce the designer baby, which usually varies between 12 and 18 months, if indeed it is achieved. That time may be excessive to treat active tumour processes, especially acute leukaemias.

Furthermore, most cases require the mother to have several ovarian stimulation cycles to obtain a sufficient number of eggs. This may entail medical risk for her, especially as ovarian hyperstimulation syndrome can develop, a serious condition which in some cases, although rare, may even lead to death. The literature[26] also reports that errors can occasionally occur in the preimplantation genetic diagnosis, and may happen on 1% to 5% of occasions. An additional difficulty is the lower probability of achieving pregnancy as the mother's age increases, which is most significant after 40, an age at which many women resort to this medical practice. According to the literature, the possibility of achieving pregnancy is 15%[27], 19%[26, 28] and 20%[4].

Negative side effects

These are minimal and most of them, as we will discuss below, are those derived from in-vitro fertilisation itself and the use of preimplantation genetic screening. However, in 2007, the first case of graft-versus-host disease was described after the transplant of umbilical cord blood derived from a designer baby[29].

ETHICAL ASSESSMENT

All human acts must unquestionably pass through a screen of their ethical suitability. As is logical, the production of designer babies is not exempt from this.

In our opinion, the eight most important aspects to consider in an ethical reflection on the production of designer babies are: 1) the instrumentalisation of the child produced in such a way that these children would be treated as commodities; 2) the secondary consequences that could result from the legal authorisation of this technique could open the door to other ethically unsuitable techniques, especially sex selection, 3) the benefit that the parents may obtain; 4) the impossibility of obtaining the consent of the child itself; 5) the medical problems that the use of the preimplantational genetic diagnosis technique may cause in the embryo generated; 6) as well as those inherent in the in-vitro fertilisation technique; 7) the negative ethical burden involved in the high number of embryos lost with this practice, i.e. the high number of human lives destroyed; 8) and finally, whether or not a medical alternative to the production of designer babies exists, since if so, their generation would be doubly unjustified.

1) Possible instrumentalisation of the designer baby produced.

A generally agreed upon ethical opinion is that the production of a designer baby is exploiting the existence of a human individual, it is treating it as an object, something that in the opinion of most authors is incompatible with the dignity that every human being has by their very nature. This ethical difficulty arises from the fact that the designer baby would not be produced thinking specifically of its own good, but as a means, an instrument, to achieve a different end, which is to be used to try to cure a sick sibling. This secondary purpose, in itself good, but far from the primary good of the baby produced, does not reconcile the practice completely, which has the aim of making it possible for the child to live. In some way, with this action, the production of a designer baby would be acting against the well-known Kantian imperative[30] which states that "a human being can never be used as a means only and must be treated as an end in itself". With the instrumentalisation that the creation of a designer baby involves, an ethical rule that should always be respected would be violated.

In accordance with this, the production of a designer baby would ethically fit within utilitarianism[31], a theory especially rooted in the anglo-saxon world, whereby the end justifies the means. This utilitarian ethic opposes that other personalist ethic in which the respect for human life, based on the dignity inherent to its own nature, is the fundamental ethic that should guide the entire process. This ethical criterion of instrumentalisation of the child produced is that which invalidates the overall goodness of the action i.e. that which conditions the ethical assessment of the production of a designer baby is, in our opinion, negative.

In order to get around this ethical stumbling block, a large group of anglo-saxon authors proposed the idea that using these children to save the life of their sibling reconciled the process as a whole, so they consider that it is very important to change the concept of "designer baby" to that of "saviour siblings"[6, 32], a brother or sister capable of donating life-saving tissue to an existing child or "donor babies"[33].

To make the production of designer babies ethically admissible, they also used the grounds that in the production process, the love of the parents towards the child generated prevails, so for this reason they also proposed that these children be called "loved children". Following this criterion, producing a designer baby would be ethically acceptable if the child was produced as a consequence of an act of love by its parents towards it, regardless of the fact that it could then be used to treat a sick sibling. The European Society of Human Reproduction and Embryology (ESHRE), in their ethical guidelines, Ethics Task Force number 5[34], also subscribe that "the creation of designer babies would be ethically acceptable if its possible use as an umbilical cord blood donor to treat a sick sibling is not the only motive for the parents to have the child". If the parents love and care for it to the same extent that they would love and care for any other child produced naturally, then in their opinion, the generation of the designer baby would be ethically acceptable. This opinion was ratified in their ninth report in 2005[26], although highlighting that the ethical assessment of the production and use of designer babies is particularly complex, since the interests of the sick child who requires the transplant should be balanced with those of the donor baby. Furthermore, it adds that if the parents lovingly

wish to have the designer baby, its production to treat the sick sibling should not be considered disrespectful towards the child, so the ethical assessment of the production of designer babies would be conditioned by the ultimate motive of the parents for the production of their child, something which in our opinion, avoids the objective ethical assessment of the production and use of the child in question.

However, in relation to the statement that the child was produced for love, it seems that it is extremely difficult to accurately define the ultimate intention of the parents to have the child, and even more so to state that the primary reason for its production is the love towards the child generated. Thus, in the case of the first designer baby, Adam Nash, who was produced when his sister Molly was 6-years-old[11], can it be reasonably sustained that in those six years his parents did not wish to have another child for love of it and that that love was only manifested when his production was required to save his sister Molly? The same, and with even greater cause, can be stated in the case of the Spanish designer baby born in Tenerife, who was produced when the sick sibling was 14-years-old[20]. Does it not seem strange that in that long period of time the parents had not wished to have their future child for love of it?

For these reasons, the editor of the “Bulletin of Medical Ethics”, Richard Nicholson, very much against this thesis, stated[35] that “we are not creating the saviour sibling to be a child in the correct sense. We are creating it to obtain a source of tissues that could be donated to an already existing child, so I do not find any moral distinction between slavery and production, therefore I prefer to call these children “slave siblings”.

2) Benefits for the couple.

Other authors consider that the ethical judgement that the production of a designer baby is worthy of is not only established for the benefit that a sick sibling could obtain, but also for the benefit that their parents may achieve[36], something that to us seems incompatible with the usual unselfish love of parents for their children.

3) The slippery slope argument.

For other authors, another argument against permitting the deliberate creation of designer babies is that to do so would be to step onto a slippery slope towards allowing parents to use embryo testing to choose other characteristics of the baby, such as eye colour and sex[37]. This has come to be known as the "slippery slope"[38,39]. In our opinion, special care would have to be taken if we slide down that slope towards the selection of sex, something which in the opinion of most authors, including ourselves, merits an absolutely negative ethical assessment, as it is a clearly eugenic technique.

4) Consent of the designer baby itself.

A crucial topic in bioethics is the consent of the patient for any action which is to be performed on them. Without this consent, any medical action upon them would be ethically unacceptable. Therefore, D Josefson[40] considers that the creation of designer babies "constitutes a violation of the rights of the donor child who cannot give its consent for this action" i.e. for it to be produced.

5) Ethical problems related with the negative side effects of in-vitro fertilisation.

It is common for those who oppose the deliberate creation of designer babies to make claims about the welfare of those children who will be thus created; therefore we are under obligation to address the association between assisted reproductive technology and birth defects. It is well known that children born using in-vitro fertilisation have more secondary problems than those conceived naturally[41]. Two reviews that included most of the existing literature on this topic found an increased risk of birth defects overall after the use of IVF[42, 43]. More recently, Reefhuis et al[44] reported that singleton birth by assisted reproductive technology was associated with septal heart defects, cleft lip with or without cleft palate, oesophageal atresia and anorectal atresia.

Therefore we can ask the question, is it ethically admissible to produce a child that could suffer such medical disorders, when the purpose of its production is not its own good, but an instrumental end to serve as an organic source of haematopoietic tissue to treat another child that has already been born, in this case the sick child? In our opinion, this is an additional ethical difficulty that should be taken into consideration when trying to assess the moral goodness of producing designer babies, since their production should take into account whether there are problems for the health of the child produced.

6) Ethical problems related with the technique of preimplantational genetic diagnosis itself.

It has already been mentioned that to find out whether the embryos created suffer from their sibling's illness or not, or whether they are histocompatible with them, a blastomere of the embryos produced when they have between 8 and 16 cells is obtained. This blastomere is used to analyse whether the embryo is biologically useful for transfer. Removal of a blastomere is not logically salutary to embryo development. Even if performed impeccably, there are fewer cells at a stage when cell numbers must increase. In addition, the means used to breach the zona pellucida could be deleterious to the embryo and the environmental changes occurring while the embryo is micromanipulated outside the incubator can also suppose a risk.

Therefore, although these embryos can implant, this is not always achieved, i.e. their viability is not annulled, but it is reduced, which leads to the percentage of pregnancies obtained being lower than those obtained if preimplantation genetic screening is not used[45, 46, 47].

Furthermore, the effects of preimplantation genetic screening are still unknown in the long term[48]. This has meant that the use of preimplantational genetic diagnosis is questioned if there is no medical reason provided that justifies it. Therefore, in the case of designer babies, we can ask the same question as we previously asked when talking about in-vitro fertilisation: is it ethical to subject an embryo to technical manipulation which reduces its viability, when such intervention is not directly aimed at its own good? It therefore seems to us that, as in the previous case, this technical difficult adds another negative reason to the production of designer babies.

7) Number of embryos lost

It is a startling fact that the broad ethical discussion that the production of designer babies provokes, especially in anglo-saxon literature, scarcely refers to the number of embryos, human lives, that are lost with this technique as a result of its low efficiency. Thus, it can be verified that in the case of the first designer baby[4], 33 embryos were used to obtain a useful child. In other words, the efficiency of the method, in the case of Adam Nash, was approximately 3%. This low efficiency is also confirmed in data published by other authors[49] (Table 3), which was 1.07%. However, unquestionably the most demonstrative datum is that published in 2005 in a study which collected the joint data from some of the leading reproductive medicine clinics in the world in which designer babies are produced[50]. This showed (Table 4) that from 1130 embryos, only 35 designer babies were obtained, which indicates that the efficiency of production of these children was 1.15%. Similarly, the efficiency in the case of the first designer baby produced in Spain[20] was 2.17% (Table 5). In other words, if we take that reported in Table 6 as fact, it can be stated that to produce one useful designer child, 98.85 human embryos have to be destroyed, something that in our opinion is ethically unacceptable, especially if we consider that in medicine there are alternative possibilities to the production of a designer baby to cure its sick sibling.

ALTERNATIVES TO THE PRODUCTION OF DESIGNER BABIES

Since trying to cure a sick child is a commendable medical aim and because for the moment it is not always possible to have a histocompatible family member, it should be determined whether in that case there is another reasonable possibility for treating the

patient other than the production of a designer sibling, or if it would be ethical to stop treating the child in question, even though that could lead to death due to not using a method which may be ethically unacceptable i.e. the production of a designer baby.

Considered like this, the answer is not easy, but that dilemma, in our opinion, is erroneous in its approach, since in most cases these children can be treated using umbilical cord blood from public banks. In 2007, there were already more than 40 public umbilical cord blood banks in the world[51,52] with more than 400,000 units available and more than 20,000 umbilical cord blood transplants performed in children and adults[53]. Today it is thought that there may be more than 50[53]. Therefore, it is reasonable to think that it is very likely that these banks have a unit of umbilical cord blood compatible with the sick child, since according to some estimations, the optimal number of units is currently estimated at 50,000 for a population of 60 million inhabitants[53]. However, the optimal number of cord blood units should approach 9 per 100,000 inhabitants[54]. This number should increase in relation to the number and origin of ethnic minorities in each country.

The crucial question is to know if, in the event that there were sufficient umbilical cord blood samples stored and these were properly identified antigenically, there would still be a need in a specific case for producing a designer baby to treat a certain sick child.

To be able to get around this need, as well as increasing the number of units stored in the public umbilical cord blood banks, their antigenic identification could also be improved. In effect, to determine whether these samples are immunologically compatible

with the blood of the sick child, a certain number of histocompatibility antigens must be determined. The higher this number, the more likely it is for the transplant to be successful. At present, four antigens are generally identified to reduce costs, but six or eight (or even twelve) could be identified.

Therefore, the specific question would be: if the abovementioned conditions were met, an increase in the number of umbilical cord blood samples stored and a more leucocyte antigens identified, would there still be any specific cases in which it would not be possible to find an umbilical cord blood sample suitable for the sick child, and consequently, if they had to be treated, would it be unavoidable to resort to the production of a designer baby? In our opinion, we think that this is unlikely.

However, as well as the above consideration, it should be remembered that the efficiency of the technique for the production of designer babies, as discussed previously, is very low, less than 2%, so another fact to take into account to establish a definitive ethical opinion on the production of designer babies is that if there were no possibility of finding a suitable umbilical cord blood sample, something fortunately doubtful, being able to produce the correct designer baby is not easy, since in many cases, after four or five attempts to obtain the desired baby, this is not achieved. This could undoubtedly cause the parents unquestionable psychological stress which could lead to a worse state of mind than they had when they decided to try to have their designer baby. For this reason, it seems to us that we must try to find the necessary technical means so that a suitable umbilical cord blood sample can be available for every sick child. This, I believe, is the medical objective to achieve, and I

have no doubt that it will be, since most technical requirements, when medically necessary, are attained. If this is so, I believe that it could be said that it will be science itself, the very science that gave rise to the possibility of producing designer babies, which will find the right ways so that it is not necessary to produce them.

TABLES

Table 1

Table 2

Table 3

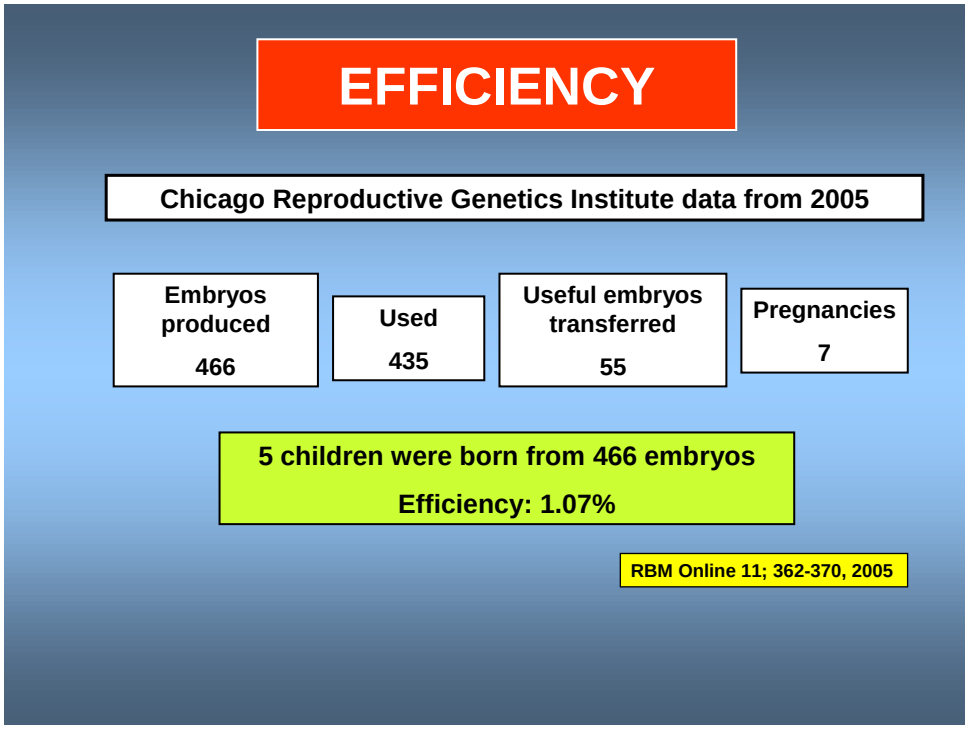


Table 4

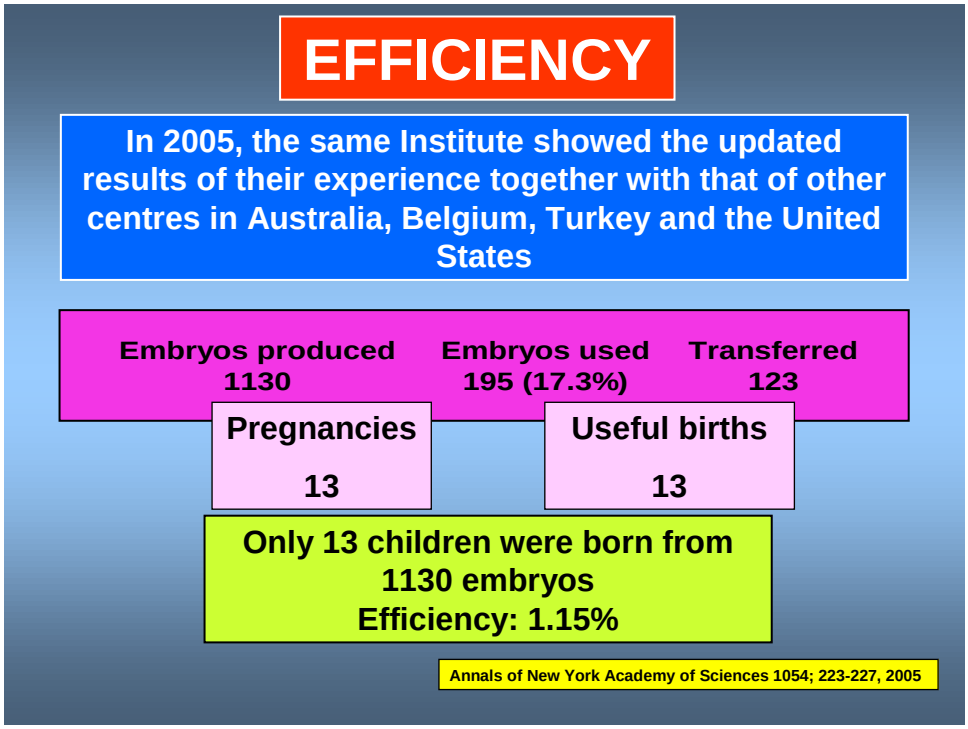
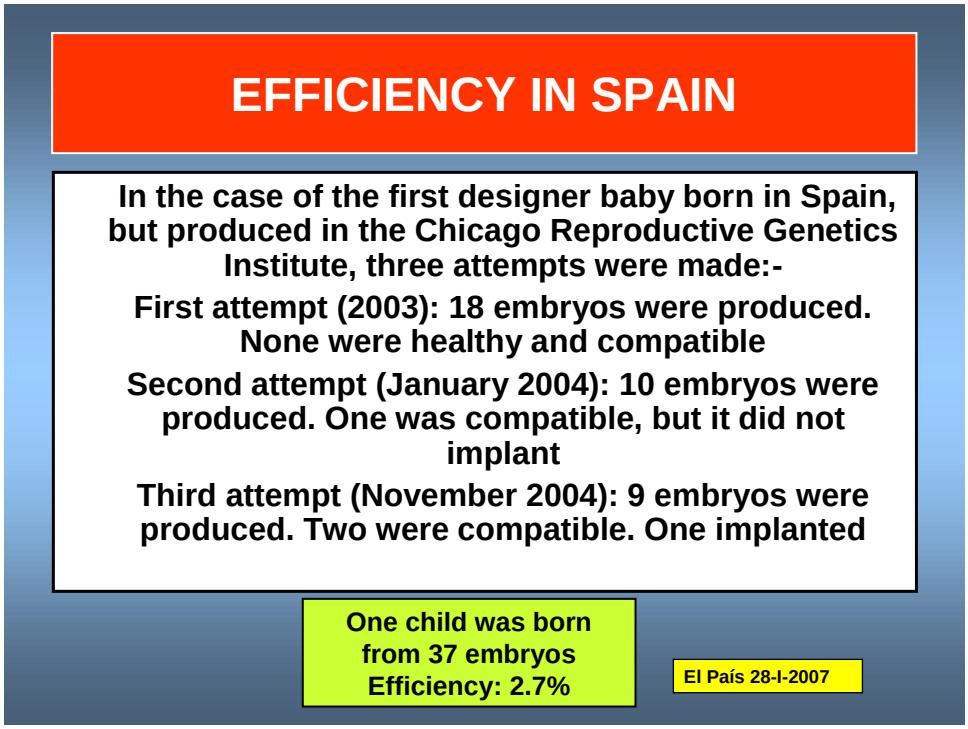


Table 5


EFFICIENCY IN SPAIN
In the case of the first designer baby born in Spain, but produced in the Chicago Reproductive Genetics Institute, three attempts were made:-
First attempt (2003): 18 embryos were produced. None were healthy and compatible
Second attempt (January 2004): 10 embryos were produced. One was compatible, but it did not implant
Third attempt (November 2004): 9 embryos were produced. Two were compatible. One implanted
One child was born from 37 embryos
Efficiency: 2.7%
El País 28-I-2007

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