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BANCOS DE SANGRE DE CORDÓN UMBILICAL. ASPECTOS ÉTICOS. BANCOS PÚBLICOS VERSUS BANCOS PRIVADOS

UMBILICAL CORD BLOOD BANKS. ETHICAL ASPECTS. PUBLIC VERSUS PRIVATE BANKS

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Resumen

La creación de bancos de sangre del cordón umbilical (UCB), plantea interesantes problemas médicos, sociales, económicos y éticos. Este documento analiza los problemas éticos en particular. En este sentido, se evalúa: a) si hay ventajas en el uso de la UCB en comparación con la médula ósea, b) si es o no es ético crear bancos de SCU, c) si su creación es éticamente aceptable en términos de su utilidad clínica o d) el uso de los mismos con fines terapéuticos, y finalmente, e) si su creación está éticamente justificada desde el punto de vista costo / rentabilidad. Nos centramos principalmente en la evaluación de la controversia ética entre los bancos públicos y privados, y en particular sobre si es ético almacenar sangre autóloga en bancos de SCU privados, sobre la base de sus limitadas posibilidades de uso por parte del donante de sangre del cordón umbilical. Desde el punto de vista ético, se puede concluir que los bancos de sangre autóloga tiene una limitada aceptación entre investigadores especializados, sociedades científicas y otras instituciones públicas, por lo que nos parece, que es éticamente más adecuado apoyar la creación de bancos públicos de SCU, por razones médicas y sociales y, sobre todo basado en el principio de justicia y solidaridad humana. Sin embargo, no hay ningún argumento ético definitivo por qué una pareja, de acuerdo con su autonomía y libertad, no puede almacenar la SCU de su hijo en un banco privado. Una solución igualmente aceptable podría se la creación de bancos mixtos, como el propuesto por Virgin Health Bank o como los españoles

en donde las muestras autólogas se pueden almacenar en bancos públicos, pero con la condición de que si en un momento determinado la muestra almacenada fuera requerida por otra persona ajena al donante, habría que dársela.

Palabras clave: bancos de sangre de cordón umbilical, bancos públicos de sangre de cordón umbilical, bancos privados de sangre de cordón umbilical, aspectos éticos.

Abstract

The creation of umbilical cord blood (UCB) banks raises interesting medical, social, economic and ethical issues. This paper reviews the ethical problems specifically. In this respect, it evaluates: a) whether there are advantages to the use of UCB compared to bone marrow, b) whether or not it is ethical to create UCB banks, c) whether their creation is ethically acceptable in terms of their clinical usefulness or d) the use made of them for therapeutic purposes, and finally e) whether their creation is ethically justified from a cost/profitability point of view. We focus primarily on evaluating the ethical controversy between public and private banks, particularly on whether it is ethical to bank autologous blood in private UCB banks, on the basis of its limited possibilities for use by the cord blood donor. We can conclude that, from an ethical point of view, autologous blood banks have limited acceptance among specialised researchers, scientific societies and other public institutions. Therefore, we believe that it is ethically more acceptable to support the creation of public UCB banks for medical and social reasons and, above all, based on the principle of justice and human solidarity. Nevertheless, there is no definitive ethical argument why a couple, according to their autonomy and freedom, cannot bank their child's UCB in a private bank. An equally acceptable solution could be the creation of mixed banks, such as that proposed by the Virgin Health Bank or like the Spanish system where autologous samples can be stored in public banks but with the proviso that if at any time the stored sample is required by any person other than the donor, it would have to be given to them.

Key Words: Umbilical cord blood banks. Public umbilical cord blood banks. Private umbilical cord blood banks. Ethical aspects.

1. Introduction

Since the first umbilical cord blood (UCB) transplant was carried out in 1988, UCB has been known to be a useful source of stem cells for treating patients who require transfusions of haematopoietic material, both children and adults. As a result, this type of biological material is being increasingly used in clinical medicine[1]. This therapeutic reality aroused our interest in the ethical evaluation of the use of UCB, especially

1 Wagner JE, Gluckman E «Umbilical cord blood transplantation: The first 20 years.» *Seminars in Hematology 4, (2010); 3-12.*

the ethical aspects related with both types of existing UCB banks: public and private.

2. Ethical aspects related with UCB banks

Several aspects can be considered on assessing the ethicality of the creation of UCB banks: 1) whether their creation and maintenance is clearly ethical, regardless of whether they are public or private, 2) the ethicality of public versus private banks, 3) various general ethical aspects related with the rights of donors and their children.

2.1. Is it ethical to create UCB banks, either public or private?

The first ethical aspect to consider is whether it is necessary at present to create UCB banks, either public or private.

From a clinical point of view, it is not always possible to find a histocompatible relative who can donate UCB to treat another family member who requires this treatment, since only 30% find a matching donor [2], thus making it necessary to develop other alternatives. Among these, the ideal solution is to create allogeneic HPC banks, i.e. from people unrelated to the patient requiring transplantation.

To carry out this evaluation, four fundamental aspects can be considered:

1. Advantages and disadvantages of the use of UCB in relation to bone marrow (BM) and G-CFS mobilized peripheral blood from fully matched and haplo-identical donors.
2. Ethical justification for the creation of UCB banks in terms of their clinical usefulness.
3. Ethical justification for their creation in relation to their use, i.e. whether they are used to the extent previously hoped for.
4. Ethical assessment of the cost effectiveness of the storage and use of the conserved samples.

2.1.1. Ethical assessment of the use of UCB with respect to BM. Advantages and disadvantages

The first question that can be asked is if, in view of the large number of duly identified BM samples that currently exist (now in excess of 18 million), it is also necessary to promote the conservation of UCB samples, and if so, what reasons might there be for this? Therefore, we consider it imperative to first evaluate whether the use of UCB offers advantages over the use of BM, since if this is the case, regardless of the large number of BM samples that already exist in specific donor registers, the conservation of UCB samples would also be justified.

According to Wagner and Gluckman, in a review of the first 20 years of umbilical cord blood transplantation[3], the following were confirmed advantages of UCB;

a) the absence of any risk for the UCB donor and the lower risk of transmission

2 Sullivan MJ «Banking on cord blood stem cells» *Nature Reviews Cancer 8, (2008), 554-563.*

3 Wagner JE, Gluckman E, op.cit. 1.

of an infection by pathogens for the recipient.

b) banked HLA-typed UCB was immediately available; c) UCB collections could be targeted, a potential strategy for overcoming the under-representation of many ethnic and racial minorities plaguing most adult volunteer donor registries.

Other «benefits», however were more speculative than known, namely: a) UCB would contain enough hematopoietic stem and progenitor cells to engraft most adults and children; b) UCB would be associated with less graft-versus-host disease (GVHD) as the neonate is immunologically «naïve»; c) HLA matching would be less stringent, again because of the immunological naiveté, although these benefits are already well established.

Nonetheless UCB was also associated with potential risks. Interestingly, the many opponents of UCB argued vehemently that the immunological naiveté of UCB would result in higher relapse rates and risks of opportunistic infection. Other opponents argued that maternal cell contamination would result in life-threatening acute GVHD. However, it would be the high likelihood of graft failure that would most severely limit the usefulness of UCB, due to the low absolute numbers of hematopoietic stem cells and progenitors.

In summary, there does not appear to be any ethical difficulty in promoting the use of UCB together with BM, given the potential advantages of UCB with respect to BM.

2.1.2. Ethical justification for the creation of UCB banks in terms of their clinical usefulness

There is no doubt that today the clinical usefulness of UCB is widely justified[4], since it can be used to treat acute and chronic leukaemias[5,6,7] myelodysplastic syndromes[8], β-thalassaemia major[9,10], Fanconi anaemia[11,12], sickle cell anaemia[13,14], severe bone marrow

4 Ibid 1.

5 Laughlin MJ, Eapen M, Rubinstein P et al. «Outcomes after transplantation of cord blood or bone marrow for unrelated donors in adults with leukemia.» *New England Journal of Medicine 351, (2004), 2265-2267.*

6 Advani AS, Laughlin MJ. «Umbilical cord blood transplantation for acute myeloid leukemia.» *Current Opinion in Hematology 16, (2009), 124-128.*

7 Atsuta Y, Suzuki R, Nagamura-Inoue T et al. «Disease-specific analyses of unrelated cord blood transplantation compared with unrelated bone marrow transplantation in adult patients with acute leukemia.» *Blood 113, (2009), 1631-1638.*

8 Parikh SH, Mendizabal A, Martin PL et al. «Unrelated donor umbilical cord blood transplantation in pediatric myelodysplastic syndrome: a single-center experience.» *Biology of Blood and Marrow Transplantation 15, (2009), 948-955.*

9 MacMillan ML, Walters MC, Gluckman E «Transplant outcomes in bone marrow failure syndromes and hemoglobinopathies» *Seminars in Hematology 47, (2010), 37-45.*

10 Boncimino A, Bertaina A, Locatelli F «Cord blood transplantation in patients with emoglobinopathies» *Transfusion and Apheresis Science 42, (2010), 277-281.*

11 MacMillan ML, Walters MC, Gluckman E, op.cit. 9.

12 Gluckman E, Rocha V, Ionescu I et al. «Results of unrelated cord blood transplant in Fanconi anemia patients: risk factor analysis for engraftment and survival.» *Biology of Blood and Marrow Transplantation 13,(2007), 1073-1082.*

13 Ibid 9.

14 Boncimino A, Bertaina A, Locatelli F, op.cit. 10.

aplasia[15,16], lymphoproliferative disorders[17], severe immunodeficiency syndrome[18,19], autoimmune diseases[20], severe metabolic disorders[21,22,23] and also cancers and other solid tumours[24, 25].

This ample potential for clinical use appears to ethically justify the use of UCB for therapeutic purposes and, consequently, the creation of banks of this haematopoietic material.

Similarly, clinical trials currently underway in patients with neonatal brain damage[26] and diabetes type 1[27] may eventually support the ethicality of the use of UCB, although at present the results are very tentative and further more extensive studies are required to confirm them[28].

From an ethical point of view, regardless of the use of UCB in various pathologies, an important aspect to consider is whether the results obtained could justify its use. In this respect, the specialised literature shows that the average engraftment when UCB is used is 75% to 80% for children with leukaemia, 28% to 78% for adults with leukaemia and 70% to 80% for non-malignant diseases, and that the survival is 49% to 55% for children, 75% for adults and 80% for non-malignant diseases[29]. However, although transplant consolidation is slower when UCB is used than with BM, the incidence of GVHD is lower with UCB[30]. Moreover, UCB transplant can be carried out with

15 Ibid 9.

16 Yoshimi A, Kojima S, Taniguchi S et al. «Unrelated cord blood transplantation for severe aplastic anemia.»*Biology of Blood and Marrow Transplantation 14, (2008), 1057-1063.*

17 Gratwohl A, Baldomero H «European survey on clinical use of cord blood for hematopoietic and non-hematopoietic indications» *Transfusion and Apheresis Science 42, (2010), 265-275.*

18 Cairo MS, Rocha V, Gluckman E et al. «Alternative allogeneic donor sources for transplantation for childhood diseases: unrelated cord blood and haploidentical family donors». *Biology of Blood and Marrow Transplantation 14, Supplement, (2008), 44-53.*

19 Smith AR, Gross TG, Baker KS «Transplant outcomes for primary immunodeficiency disease.» *Seminars in Hematology 47, (2010), 79-85.*

20 Gratwohl A, Baldomero H, op.cit. 17.

21 Cairo MS, Rocha V, Gluckman E et al., op. cit. 18.

22 Beam D, Poe MD, Provenzale JM et al. «Outcomes of unrelated cord blood transplantation for X-linked adrenoleukodystrophy.» *Biology of Blood and Marrow Transplantation 13, (2007), 665-674.*

23 Escobar ML, Poe MD, Provenzale JM et al. «Transplantation of umbilical cord blood in babies with infantile Krabbe's disease.» *New England Journal of Medicine 352, (2005), 2069-2081.*

24 Ibid 17.

25 Ibid 18.

26 Cord blood for neonatal hypoxic-ischemic encephalopathy Duke University, Clinical protocol: NCT00593242 www.clinicaltrials.gov

27 Haller MJ, Viener HL, Wasserfall C at al. «Autologous umbilical cord blood infusion for type 1 diabetes» *Experimental Hematology 36 (6), (2008), 710.*

28 Ministero del Lavoro, della Salute e delle Politiche Sociali «Uso appropiato delle cellule staminali del sangue del cordone ombelicale» *Elementi informativi essenziali. 14-05-2009.*

29 Kurtzberg J, Lyerly AD, Sugarman J «Untying the Gordian knot: policies, practices, and ethical issues related to banking of umbilical cord blood» *The Journal of Clinical Investigation 115, (2005), 2592-2597.*

30 Rocha V, Wagner JE, Sobocinski KA et al. «Graft-versus-host disease in children who have received a cord-blood or bone marrow transplant from an HLA identical sibling» *New England Journal of Medicine 342, (2000), 1846-1854.*

fewer matched HLA antigens, although ideally at least 5 of the 6 antigens should be matched and the UCB units should contain not less than 2.5 x 10^7 nucleated cells. When these criteria are met, the transplant can be successful in more than 50% of patients[31].

Hence, prominent authors like John Wagner and Eliane Gluckman declare that «umbilical cord blood has now become one of the most commonly used sources of hematopoietic stem cells for allogeneic transplantation»[32].

Therefore, it seems that the use of UCB and the creation of banks for this type of biological sample, in terms of their clinical usefulness, can be ethically justified.

2.1.3. Ethical justification for the creation of UCB banks in terms of their clinical use

An undeniably interesting aspect to consider in the ethical justification for the creation of UCB banks is whether these are clinically used to a sufficient extent.

This appears to be widely justified, since from the creation of the first UCB bank in New York in 1993[33], the number of samples stored in public banks has been gradually growing; thus in 1997 there were already 11,000 samples, 22,000 in 1998, 38,000 in 1999, 64,000 in 2000, 87,000 in 2001, 128,000 in 2002, 165,000 in 2003, 189,000 in 2004, 212,000 in 2005, 252,000 in 2006, 262,000 in 2007, 339,000 in 2008, 408,000 in 2009, 450,000 in 2010 and 456,000 in 2011 (not all years computed)[34].

Moreover, their clinical use has also gradually increased, as the latest data indicate that more than 20,000 units have already been utilised for clinical purposes[35].

In addition, there are currently more than 100 active UCB banks worldwide[36] and the number of hospitals where UCB samples can be collected has grown substantially. At present there are more than 3500 hospitals located in more than 80 countries authorised to collect UCB samples[37].

Consequently, and in accordance with all of the above, it seems reasonable to accept that the creation of UCB banks is ethically justified in terms of the clinical use of the samples stored in them.

2.1.4. Ethical assessment of the cost-effectiveness (cost/ benefit) of the storage and use of UCB samples deposited in public banks

The first aspect to consider in this point is whether the number of samples that would be needed to meet the clinical requirements of a certain population can

31 Querol S, Mufti GJ, Marsh SGE et al. «Cord blood stem cells for hematopoietic stem cell transplantation in the UK: how big should the bank be?» *Haematologica 94, (2009), 536-541.*

32 Ibid 1.

33 Rubinstein P, Rosenfield RE, Adamson JW et al «Stored placental blood for unrelated bone marrow reconstruction.» *Blood 81, (1993), 1679-1690.*

34 Total number of cord blood units Bone Marrow Donors Worldwide (http://www.bmdw.org/index.php?id=statistics_cordblood)

35 Gluckman E, Rocha V «Cord blood transplantation: state of the art» *Haematologica 94, (2009), 451-454.*

36 Katz G, Mills A «Cord blood banking in France: Reorganizing the national network» *Transfusion and Apheresis Science 42, (2010), 307-316.*

37 Katz G, Mills A, op.cit. 36.

be reasonably obtained, since if not, it would be difficult to ethically justify the promotion of this type of facility. In fact, it appears that this is easily achievable, since it is estimated that 50,000 units of UCB would be sufficient to meet the needs of a population of around 60 million inhabitants[38].

Another aspect to consider in this field is whether the financial investment necessary to reach the number of UCB samples required to cover the clinical needs of society would be ethical.

If we begin with economic data from Spain[39], the minimum cost of storage of one UCB unit is 1300 €. The maintenance cost per year is 40 €. These costs have been calculated considering that 50% of the units extracted are discarded, a percentage that in principle can be considered as optimal, but which in many cases is not attainable. So, if we consider that the percentage of samples discarded may increase, it can be concluded that if 65% are discarded, the storage price for one unit will increase to 1600 €, and to 1900 € if 80% are discarded[40]. Therefore, making an approximate economic assessment, with an estimated discard rate of 50% and 50,000 units stored, if around 200 units are used per year, the cost per unit would be around 20,000 €[41].

According to the previous data, the minimum cost for storing 50,000 UCB units (the amount required to meet the clinical requirements of a population of 60 million inhabitants) would be around 65 million Euros[42], assuming a discard rate of 50%. Undoubtedly, these costs would have to be added to the costs required to prepare the hospital logistics necessary for sample extraction and delivery to the blood bank.

Thus, we believe that from a cost/benefit point of view, the financial investment needed to create public blood banks that store a sufficient number of samples to meet the clinical needs of any country would be ethically justified.

2.1.5. How the storage of the sample can condition its use

Another technical aspect that must be considered, but with undeniable ethical repercussions, is to determine the period of time that the stored samples can be conserved in good conditions for use, since if they deteriorate rapidly, their storage may not be ethically justified, as many would no longer be available for use when needed. In this respect, it has been shown that properly frozen samples in a technically well-equipped blood bank can be maintained in good conditions for clinical use for at least 15 years[43]. Furthermore, in a recent personal

38 Querol S, Mufti GJ, Marsh SGE et al., op.cit. 31.

39 Plan Nacional de Sangre de Cordón Umbilical http://www.ont.es/infesp/Paginas/PlanNacionalSCU.aspx

40 Querol S, Gómez SG, Pagliuca A et al. «Quality rather than quantity: the cord blood bank dilemma». *Bone Marrow Transplantation 45, (2010), 970-978.*

41 op.cit 39

42 Ibid 39.

43 Broxmeyer HE, Srour EF, Hangoc G et al. «High-efficiency recovery of functional hematopoietic progenitor and stem cells from human cord blood cryopreserved for 15 years» *PNAS 100, (2003), 645-650.*

statement, HE Broxmeyer declared that he had been able to verify the conservation of UCB samples in good conditions for up to 23 years[44]. In view of the above, it appears reasonable to conclude that, from an ethical point of view, setting up public UCB banks would be justified in relation to their creation and maintenance.

3. Ethical controversy between private and public banks

Without doubt, one of the most relevant ethical aspects in relation to UCB banks is to clarify which of them, the public or private, should be promoted first and foremost[45,46,47]. This diatribe is also necessary because it implies opposing social and personal attitudes. In this respect, the main ethical controversy centres on whether or not it is right to promote and create private autologous UCB banks.

The first point that must be considered in assessing the ethics of creating private banks is to determine to what extent the samples banked there will be able to be used in the more or less near future by the child donating the cord blood.

In relation to this, the first reports mentioned in the specialised literature estimated a probability of use of between 1/2700 and 1/20,000[48]. However, as this probability can increase with the life of the donor, subsequently calculations estimated that the possibility of the donor themselves undergoing an autologous blood stem cell transplant is 1/2700 (0.04%) up to age 20 years, 0.10% up to age 40 years and 0.25% up to age 70 years[49,50].

However, a recent study [51] reported that in 57 specialised centres in the United States and Canada in which UCB transplants are carried out, autologous UCB was only used on nine occasions. A study from the Italian ministry[52] also reported three cases of autologous transplants[53,54,55]. There may be further

44 Broxmeyer HE «Umbilical cord transplantation: Epilogue» *Seminars in Hematology 47, (2010), 97-103.*

45 Fisk NM, Roberts IAG, Markwald R et al. «Can routine commercial cord blood banking be scientifically and ethically justified?» *PLoS Medicine 2, (2005), 87-90.*

46 Ecker JL, Greene MF «The case against private umbilical cord blood banking» *Obstetrics and Gynecology 105, (2005), 1282-1284.*

47 Sugarman J, Kaalund M, Kodish E et al. «Ethical issues in umbilical cord blood banking. Working group on ethical issues in umbilical cord blood banking (review)» *JAMA 278, (1997), 938-943.*

48 Johnson FL «Placental Blood Transplantation and Autologous Banking-Caveat Emptor.» *Journal of Pediatric Hematology/Oncology 19, (1997), 183-186.*

49 Nietfeld JJ, Pasquini MC, Logan BR et al. «On the probability of using cord blood» *Biology of Blood and Marrow Transplantation 14, (2008), 724-725.*

50 Nietfeld JJ, Pasquini MC, Logan BR et al. «Lifetime probabilities of hematopoietic stem cell transplantation in the U.S.» *Biology of Blood and Marrow Transplantation 14, (2008), 316-322.*

51 Thornley I, Eapen M, Sung L et al. «Private cord blood banking: experiences and views of pediatric hematopoietic cell transplantation physicians» *Pediatrics 123: 3, (2009), 1011-1017.*

52 op.cit. 28.

53 Ferreira E, Pasternak J, Bacal N et al. «Autologous cord blood transplantation» *Bone Marrow Transplantation 24, (1999), 1041.*

54 Fruchtman SM, Hurlet A, Dracker R et al. The successful treatment of severe aplastic anemia with autologous cord blood transplantation. *Biology of Blood and Marrow Transplantation 10(11), (2004), 741.*

55 Hayani A, Lampeter E, Viswanatha D et al. «First report of autologous cord blood transplan-

unpublished cases, but we can state with almost full certainty that the clinical use of autologous UCB is currently an exception[56], since as far as we are aware, there is only one case of a duly verified autologous UCB transplant, in a four-year old girl with acute leukaemia[57].

In view of the above, it seems difficult to ethically justify the obtaining, storage and conservation of autologous UCB samples in terms of their probable clinical use, given the very low probability that they will be used.

Another important ethical aspect to consider in relation to private autologous UCB banks is the cost of a transplant of this type of haematopoietic material, taking into account the number of samples currently stored and the transplants carried out. There are presently believed to be around 800,000 UCB samples stored worldwide in private banks[58]. Furthermore, as already mentioned, there has only been one proven case of the use of autologous UCB[59] and some likely cases[60,61,62]. Moreover, it is known that conserving an autologous UCB sample in a technically well-equipped private bank for 20 years could cost around 1500 to 2000 € for banking the sample and around 150 € per year for storage[63,64], i.e. around 3000 €[65]. Consequently, storing those 800,000 UCB samples for 20 years could cost approximately 2,400 million Euros. We must therefore ask ourselves, is this financial investment to likely treat a single patient (and certainly less than a dozen) ethical?

In relation to this high cost however, it can be argued that the investment required to store and conserve the aforementioned autologous UCB samples in private banks is defrayed by the parents of the child donating the UCB. Therefore, they have the right to decide how to spend their money, especially if they use it to aid the possibility, albeit remote, of treating a son or daughter if necessary, bearing in mind the legitimate right of individuals to dispose of their own financial resources as they deem most fit, following the most elementary principles of the right to the use and enjoyment of private property as one of the fundamental guarantors of individual liberties. Even so, we are of the opinion that private money also has a

tation in the treatment of a child with leukemia». *Pediatrics 119, (2007), 296.*

56 Samuel GN, Kerridge IH, O'Brien TA «Umbilical cord blood banking: public good or private benefit?». *The Medical Journal of Australia 188, (2008), 533-535.*

57 Hayani A, Lampeter E, Viswanatha D et al., op.cit. 55.

58 Manegold G, Meyer-Monard S, Tischelli A et al. «Controversies in hybrid banking: attitudes of Swiss public umbilical cord blood donors towards private and public banking» *Archives of Gynecology and Obstetrics 284, (2010), 99-104.*

59 Ibid 55.

60 Thornley I, Eapen M, Sung L et al., op cit. 51.

61 Ferreira E, Pasternak J, Bacal N et al., op.cit. 53.

62 Fruchtman SM, Hurlet A, Dracker R et al., op. cit. 54.

63 Kurtzberg J, Lyerly AD, Sugarman J, op. cit. 29.

64 Annas GJ. «Waste and Longing- The Legal Status of Placental-Blood Banking» *The New England Journal of Medicine 340, (1999), 1521-1524.*

65 Sullivan MJ , op.cit. 2

social function, and that consequently we would have to ask ourselves if those 2,400 million Euros, even though they come from individuals, could not have been used for another more appropriate social purpose, even within the healthcare field.

3.1. Medical disadvantages of using autologous UCB samples

In addition to their limited possibility for clinical use and low cost-effectiveness, the use of autologous UCB also has some medical contraindications, as chromosomal translocations have been shown in the foetal blood of children who later developed leukaemia[66,67,68].

Therefore, the American Academy of Pediatrics has declared that the use of autologous UCB may be contraindicated due to the risk of transferring the aforementioned genetic abnormalities to the child receiving the transplant[69,70].

The various difficulties discussed up to this point have meant that the creation of private autologous UCB banks is prohibited in several countries[71], so to resolve this legal problem, some parents have chosen to send the extracted samples for conservation to countries in which the creation of private autologous UCB banks is authorised.

3.2. Could other clinical applications for autologous umbilical cord blood extend its clinical use?

We have seen that autologous UCB samples do not have many possibilities of being used for future haematopoietic transplant for the child donating the UCB sample, although they could be used for other clinical purposes, which may, as the defenders of the creation of private UCB banks suggest, extend their possibility for use. Hypothetically, the highest likelihood of using these samples is in the field of regenerative and reparatory medicine, since it has already been possible to confirm the transdifferentiation of UCB stem cells to brain, heart, liver, pancreas, bone and cartilage cells[72,73].

Thus autologous UCB, rich in adult stem cells, could be used by the patient themselves or by a relative to try to regenerate a damaged organ[74,75,76,77].

66 Zipursky A «Fetal origin of leukemia and autologous cord blood transfusions.» *Pediatric Research 47, (2000), 574.*

67 Rowley JD «Backtracking leukemia to birth» *Nature Medicine 4, (1998), 150-151.*

68 Greaves MF, Wiemels J «Origins of chromosome translocations in childhood leukaemia» *Nature Reviews Cancer 3, (2003), 639-649.*

69 Leonard MB «Glucocorticoid-induced osteoporosis in children: Impact of the underlying disease» *Pediatrics 119: Supplement 2, (2007), 166-174.*

70 Lubin BH, Shearer WT «Cord blood banking for potential future transplantation» *Pediatrics 119, (2007), 165-170.*

71 Thornley I, Eapen M, Sung L et al., op. cit. 51.

72 Porada GA, Porada C, Zanjani ED. «The fetal sheep: a unique model system for assessing the full differentiative potential of human stem cells» *Yonsei Medical Journal 45(suppl), (2004), 7-14.*

73 Kogler G. «A new human somatic stem cell from placental cord blood with intrinsic pluripotent differentiation potential» *The Journal of Experimental Medicine 200, (2004);123-135.*

74 Ibid 29.

75 Ibid 51.

76 Cord blood Registry (online) http://www.cordblood.com/ (2007).

77 Ballen KK, Barker JN, Stewart SK et al. «Collection and preservation of cord blood for personal

However, this is a possibility that has yet to be confirmed, although given the many clinical trials currently underway with adult stem cells (around 3417) and UCB (around 196)[78], it does not appear to be an exaggeration to think that for the child donating the cord blood or for some of their relatives, the stem cells contained in it could be useful in the mid- to long-term to treat possible tissues that might require reparatory treatment.

Moreover, given that UCB contains mesenchymal cells[79] from which cells of various tissues, such as bone, fat and cartilage have been able to be derived[80], this would extend its possible use to relatives, within the aforementioned field of regenerative and reparatory medicine[81]. In addition to mesenchymal cells, UCB also contains endothelial progenitor cells[82,83], which can specifically be used to repair damaged blood vessels. Nevertheless, there is still a long way to go in this area before its possible clinical application[84].

Finally, an additional possibility for the use of UCB stem cells would be to use them to generate the patient's own iPS cells (reprogrammed adult cells), from which cells of different tissues could be derived, theoretically increasing their possibility for clinical use[85,86]. However, for iPS cells derived from UCB cells to become an objective clinical reality, a series of unavoidable technical problems must first be resolved so that this step can be taken[87].

3.3. Other reasons for sustaining the ethical controversy between public and private UCB banks

In addition to the aforementioned reasons, possibly the main ethical reason which does not support setting up autologous UCB banks is that promoting them could go against a generic principle of social solidarity, on reserving the samples stored in them for the exclusive use of the donor or their family[88]. This

use». *Biology of Blood and Marrow Transplantation 14, (2008), 356-363.*

78 Clinical trials http://clinicaltrials.gov (accessed 06-07-11)

79 Bieback K, Klüter H «Mesenchymal stromal cells from umbilical cord blood» *Current Stem Cell Research and Therapy 2, (2007), 310-323.*

80 Bianco P, Robey PG, Simmons PJ «Mesenchymal Stem Cells: Revisiting History, Concepts, and Assays» *Cell Stem Cell 2, (2008), 313-319.*

81 Uccelli A, Moretta L, Pistoia V «Mesenchymal stem cells in health and disease» *Nature Reviews Immunology 8, (2008), 726-736.*

82 Au P, Daheron LM, Duda DG et al. «Differential in vivo potential of endothelial progenitor cells from human umbilical cord blood and adult peripheral blood to form functional long-lasting vessels» *Blood 111, (2008), 1302-1305.*

83 Prockop DJ. «Repair of tissues by adult stem/progenitor cells (MSCs): controversies, myths, and changing paradigms» *Molecular Therapy 17, (2009), 939-946.*

84 Prockop DJ, op. cit. 83.

85 Haase A, Olmer R, Schwanke K et al. «Generation of induced pluripotent stem cells from human cord blood» *Cell Stem Cell 5:, (2009), 434-441.*

86 Giorgetti A, Montserrat N, Aasen T et al. «Generation of induced pluripotent stem cells from human cord blood using OCT4 and SOX2» *Cell Stem Cell 5, (2009), 353-357.*

87 Saha K, Jaenisch R «Technical challenges in using human induced pluripotent stem cells to model disease» *Cell Stem Cell 5, (2009), 484-595.*

88 American College of Obstetricians and Gynecologists «Committee opinion, umbilical cord blood banking.» *Obstetrics and Gynecology 111, (2008), 475-477.*

ethical diatribe has its basis in the search for a balance between social solidarity and individual liberties. Indeed, for those who defend the promotion of public UCB banks, a fundamental ethical principle to consider is that any individual free decision should be respectful of a generic principle of social justice. Nevertheless, those who are in favour of the promotion of private autologous UCB banks believe that controversy cannot be raised between individual liberties and social solidarity, since not all free action should be subject to the principle of solidarity, although it would be desirable, since solidarity should be exercised freely. This is based on their opinion that individual liberties are above solidarity, a statement which, although reasonable, does not obviate that on occasion the lack of social solidarity conditions the ethical assessment of individual actions carried out freely, since if this principle were admitted as an absolute in relation to the creation of private UCB banks, it could lead to uncontrolled growth of private autologous UCB banks to the detriment of public banks. This could infringe on the principle of social solidarity to which we are referring, especially if we take into account the marked individualism that currently predominates our Western civilisation.

On the other hand, it can be stated that public banks, as they are financed with state funds, guarantee the possibility of addressing the health issues of all citizens, thus honouring the right of all people to health, one of the fundamental human rights.

Another ethical difficulty related with the generic principle of social justice could arise as there are women who, even though they wish to donate the UCB, cannot do so as in certain countries or regions there are no proper legal requirements or technical conditions necessary to obtain the sample.

The fact that samples to be stored in private banks (for financial reasons or profit) are not subject to the same technical controls as those stored in public banks could also pose an ethical problem, as it would probably mean that autologous UCB samples stored in private banks would be of lower quality than those stored in public banks[89].

As we have previously stated, according to data from the Spanish Ministry of Health[90], between 50% and 80% of samples are discarded in Spain as they do not meet the technical suitability specifications required for storage. Are we certain that this is not also the case with the autologous UCB samples to be stored in private banks? Are there data relating to the number of samples that are rejected as they do not have the appropriate technical specifications? We believe that this rejection, which for unquestionable financial reasons does not occur, would certainly constitute an ethically unacceptable medical act.

89 Sun J, Allison J, Mc Laughlin C et al. «Differences in quality between privately and publicly banked umbilical cord blood units: a pilot study of autologous cord blood infusion in children with acquired autologous disorders.»*Transfusion 50, (2010), 1980-1987.*

90 Ibid 39.

Another ethical question that can be posed is whether offering medical services that require a high financial investment for the users to utilise them several years later (on occasions more than fifteen) can be accepted without taking into account the possible risk that the companies that offer those services, proprietors of the autologous UCB banks, may terminate their activity due to company circumstances of any type. Thus the European Group for Ethics in Science and New Technologies recommends that given the possibility of these companies closing, it should be mandatory to provide clients with information about this possible eventuality, and insurance should guarantee the continuity of sample storage or the power to transfer them to another bank, in addition to compensating the clients adequately if necessary[91].

Finally, another important point to take into consideration is whether private banks offer adequate information to their potential clients about all the medical and ethical aspects related with the collection and storage of UCB samples. In relation to this, a systematic review of web pages published in English including data from 148 commercial banks confirmed that the information given to clients is, on many occasions, confusing and potentially erroneous, possibly motivated by the financial benefits to be obtained[92].

This potentially deceptive information extends to offering lists of possible diseases that can be treated with UCB, including cancer, bone marrow failures and genetic diseases, without there being medical evidence for this to date, as most of these diseases can only be treated with allogeneic UCB transplants. Equally, most commercial banks also offer the possibility of using autologous UCB for numerous diseases which could be treated in the future within the field of regenerative and reparatory medicine[93], although as has already been mentioned, this is still a hypothetical possibility far from having been confirmed. A positive exception in this turbulent field of private UCB banks may be the Virgin Health Bank, which as will be discussed later, offers a mixed solution and true and clear information[94].

3.4. Alternatives to the use of private banks

A possible alternative to make the conservation of autologous blood in private banks more ethical is the proposal by the English Virgin Health Bank[95,96], in which 80% of the sample stored is reserved for allogeneic public use and 20% for private autologous use. The aforementioned proposal has, at present, the disadvantage that the 20% reserved for

91 European Group on Ethics in Science and New Technologies to the European Commission. Ethical aspects of umbilical cord blood banking (http://ec.europa.eu/European_group_ethics/docs/avis19_en.pdf)

92 op.cit. 88.

93 Manegold G, Meyer-Monard S, Tischelli A et al. op. cit. 58.

94 Editorial «Umbilical cord blood banking Richard Branson's way» The Lancet 369, (2007), 437.

95 op. cit. 94.

96 Mayor S «World's first public-private cord blood bank launched in UK by Richard Branson» *British Medical Journal 334, (2007), 277.*

autologous use may not be sufficient to meet its therapeutic objective. However, to resolve this limitation, scientists are actively working, as are Virgin, on the development of cell expansion techniques[97,98] that may increase the cellularity of the samples to thereby make them clinically useful. Richard Branson, proprietor of Virgin Bank, donates 50% of the profits from Virgin Bank to research aimed at increasing the therapeutic potential of UCB[99].

Some countries, among them Spain, offer the possibility of conserving the autologous sample in a public bank, but with the condition that if at a determined moment said sample should be required for a patient unrelated to the donor's family, there would be a legal obligation to give it to them. Thus, there would be the risk that the autologous blood that was conserved for the priority use of the donor or their family would be unable to fulfil its purpose on having been used by another patient. However, if this risk is voluntarily accepted, mixed public banks could be considered ethically acceptable, although it would have to be guaranteed that the blood conserved in them is properly typed so that, where appropriate, it could be assigned for an allogeneic transplant, following parental consent.

3.5. Ethical opinion that umbilical cord banks merit different public institutions or scientific bodies

In general we can state that, in view of the above, expert groups, public authorities and opinion leaders are not in favour of the promotion of private UCB banks[100,101,102].

Hence, the European Group on Ethics in Science and New Technologies states that commercial banks merit serious ethical reservations[103]. Equally, the Convention of Oviedo (article 21) is reluctant to store autologous UCB as it states that «the human body and its parts shall not give rise to financial gain» [104]. The World Association of Bone Marrow Donors also questions autologous UCB banks, as they offer a service that, at present, does not have real therapeutic use and often «promises more than they can deliver»[105].

Among the scientific institutions, the United Kingdom's Royal College of

97 Jaroscak J, Goltry K, Smith A et al «Augmentation of umbilical cord blood (UCB) transplantation with ex vivo-expanded UCB cells: results of a phase 1 trial using the Aastrom Replicell System» *Blood 101, (2003), 5061-5067.*

98 Delaney C, Heimfeld S, Brashem-Stein C et al «Notch-mediated expansion of human cord blood progenitor cells capable of rapid myeloid reconstitution» *Nature Medicine 16, (2010), 232-236.*

99 Mayor S, op.cit. 96.

100 Ibid 1.

101 Ibid 28.

102 Ibid 36.

103 op. cit 91.

104 Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Convention on human rights and biomedicine, Oviedo; 4 April 1997 http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm

105 WMDA policy statement on the utility of autologous or family CBU storage; 25 May 2006.

http://www.worldmarrow.org/fileadmin/WorkingGroups_Subcommittees/Cord_Blood_Working_Group/WMDA_Policy_Statement_Final_02062006.pdf

Obstetricians and Gynaecologists is also opposed to the creation of private UCB banks for ethical and medical reasons[106], as is the Royal College of Midwives[107]. Similarly, the Belgian Advisory Committee on Bioethics Opinion[108], the Swiss Society of Gynaecology and Obstetrics[109] and the French Academy of Medicine[110] do not advocate private banks. The American Academy of Pediatrics[111,112], the American College of Obstetricians and Gynecologists[113] and the Society of Obstetricians and Gynaecologists of Canada[114] also agree in this respect.

The Italian Ministry for Health and Social Policy, in a report on the proper use of UCB stem cells[115], also stated that: «the indications for the conservation of UCB at birth, with a view to a future autologous haematopoietic transplant are non-existent for the moment», having «at present actual scientific evidence only for the use of allogeneic blood».

4. General ethical aspects related with the donor and her child

Regardless of the ethical aspects specifically related to the promotion, development and maintenance of UCB banks, certain general ethical regulations should be taken into consideration on discussing the ethics of these banks, since the donation of UCB samples should be given the same ethical treatment as the donation of organs and tissues for biomedical research.

Since this is not the specific aim of this report, we will refer to the general ethical aspects following two recent, well-structured reviews[116,117]. In agreement with that stated therein, informed consent, the obtaining of financial benefits, ownership

106 Royal College of Obstetricians and Gynaecologists. Scientific advisory committee opinion paper 2, Umbilical cord blood banking; June 2006 http://www.rcog.org.uk/files/rcog-corp/uploaded-files/SAC2UmbilicalCordBanking2006.pdf

107 Royal College of Midwives. «Guidance Paper 1a: commercial umbilical cord blood collection.» *RCM Midwives 5, (2002), 422-423.*

108 Belgian Advisory Committee on Bioethics Opinion Nº 42 of 16 April 2007 on umbilical cord blood banks.

109 Surbek D, Seelmann K, Gratwohl A et al Société Suisse de Gynécologie and Obstétrique. «Don de sang de cordon: Don non dirigé, don familial (dirigé) et don à but de transplantation autologue («Private banking»)» Avis d'Experts Nº 10, Décembre 2002 http://sggg.ch/files/AVIS%20%D%20EXPERTS2010.pdf

110 Bourel M, Arcadillou R Rapport: Les banques de sang de cordon autologue. Académie Nationale de Médecine 19 November 2002

111 American Academy of Pediatrics. «Cord blood banking for potential future transplantation.» *Pediatrics 1, (2007), 165-170.*

112 American Academy of Pediatrics WGOCBB «Cord blood banking for potential future transplantation: subject review American Academy of Pediatrics. Work group on cord blood banking.» *Pediatrics 104, (1999), 116-118.*

113 Ibid 88.

114 Armson BA Maternal/fetal medicine committee, Society of Obstetricians and Gynaecologists of Canada. «Umbilical cord blood banking: implications for perinatal care providers» *Journal of Obstetrics and Gynaecology Canada 27, (2005), 263-290.*

115 Ibid 28.

116 American Medical Association. (presented by: Levine Mark A) Umbilical cord blood banking. Report of the Council on Ethical and Judicial Affairs. American Medical Association. CEJA Report 9-I-07. November 2007 www.ama_assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion2165.shtml

117 Petrini C «Umbilical cord blood collection, storage and use: ethical issues» *Blood Transfusion 8, (2010), 139-148.*

of the stored samples,data storage and the privacy of the donor and her child would have to be considered among others.

Obtaining informed consent from the woman donating the UCB sample is fundamental to ensure her autonomy. Said consent should be obtained prior to the onset of labour, so that the woman is in the best condition to be able to give that consent with full awareness.

The report given to the woman to sign would have to include the method to be followed to obtain the sample, how it is to be handled after it is obtained and the choice of banks available to store it, as well as the risk that, due to various medical circumstances, the UCB cannot be stored as it is not of sufficient quality.

In relation to data storage and protection, the existing regulations in most developed countries would have to be respected.

With regard to the protection of the privacy of the mother donating the UCB and her child, the same precautions would have to be taken as with blood samples obtained for any other medical purpose.

Another ethical aspect to consider is whether the relationship between the UCB bank where the sample is banked and the women who donate it should be maintained, as this could be useful in the eventual subsequent use of the conserved blood, although this relationship would have to be treated with consummate care, as there may be a risk of violating confidentiality, both mother's and child's.

The ownership of the stored UCB sample also merits ***a legal reflection***, since some people advocate that it is property of the child, as it is a part of their body, and others believe that it should be property of the mother. The first position appears to be more correct given that, in most developed countries, the child who is fully outside the mother is legally recognised as a person, with all the rights inherent to this condition, so the manipulation of part of their body should be considered as a violation of their principle of autonomy.

Finally, special caution should be taken in any relationships that health care workers responsible for advocating and obtaining the sample may have with the private banks in which the UCB is to be deposited, to prevent possible financial gains which could cloud their medical actions, if they encourage the woman to bank the sample in private banks with which they collaborate.

5. Conclusions

Many criticisms have been made of the establishment of private UCB banks from an ethical point of view, as expressed here. However, in our opinion, there is no definitive ethical argument why a couple cannot bank the umbilical cord blood of any of their children in one of these banks, invoking their right to exercise their autonomy and personal freedom. This right is reinforced by the medical reality that the best clinical response is obtained using the blood from a close relative or the patient themselves. Furthermore, the fact that autologous blood also offers the possibility of being used in the field of

regenerative and reparatory medicine by the patient themselves or a close relative may also open up further potential for use. Nevertheless, despite this, the possibilities of using an autologous blood sample are remote, a fact of which parents who wish to conserve the umbilical cord blood of their child should be made aware.

In summary, our opinion is that from an ethical point of view, promoting the creation of public umbilical cord blood banks is the ideal solution, but in a strict sense there does not appear to be any insurmountable ethical reason why some parents cannot opt to bank the blood of their child in a private bank, although always leaving it well established that public banks more adequately meet the medical and ethical purposes for which they are intended, on guaranteeing their use for all citizens, thereby fulfilling a positive principle of justice and social solidarity.

With respect to private companies that promote the creation of umbilical cord blood banks, we believe that the same ethical regulations can be applied, i.e. that there are no determinant reasons to prevent them from exercising their commercial action freely, but always respecting the unavoidable precept of informing their clients of the limited possibilities for use of autologous blood for medical purposes.

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