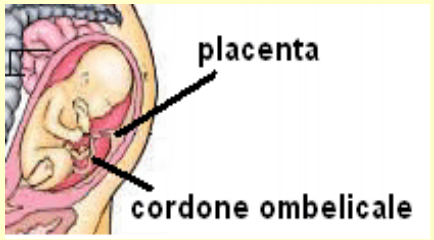
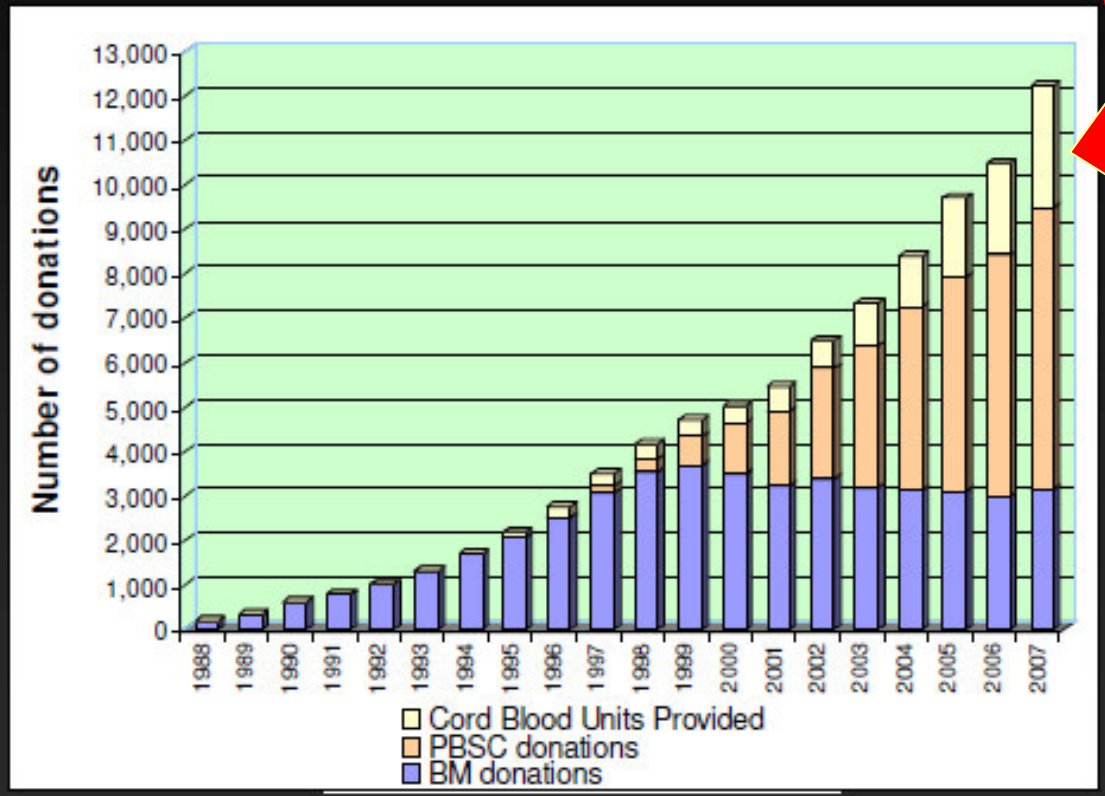
Cord blood transplant outcomes and banking policies

Paolo Rebulla, MD
Milano Cord Blood Bank
Center of Transfusion Medicine, Cellular Therapy and Cryobiology
Foundation Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy



NUMBER OF STEM CELL PRODUCTS

12,227 in 2007 for unrelated patients

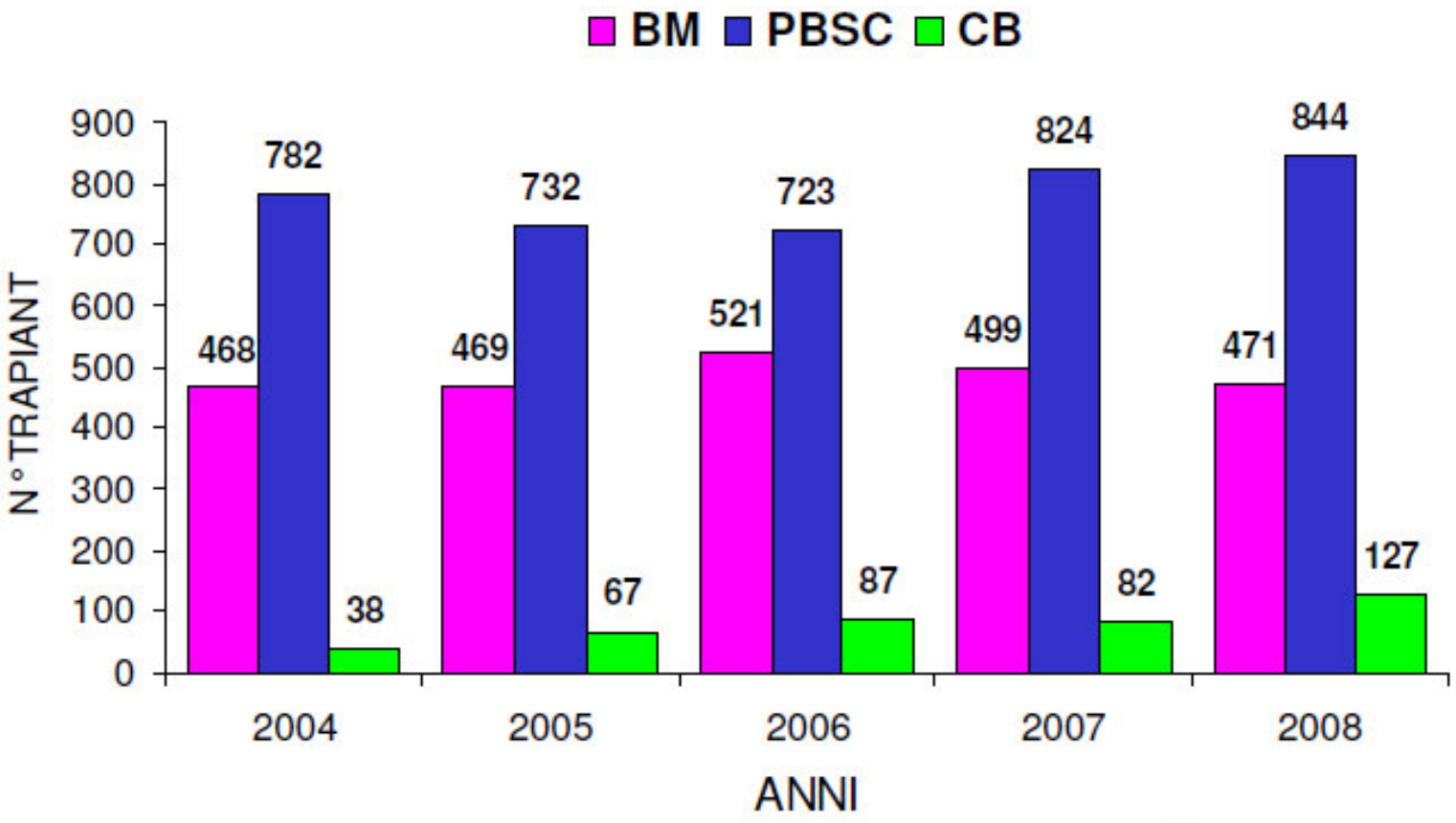


21%!

WMDA

GITMO Trapianto Allogenico

Allotrapianti per Sorgente di CSE



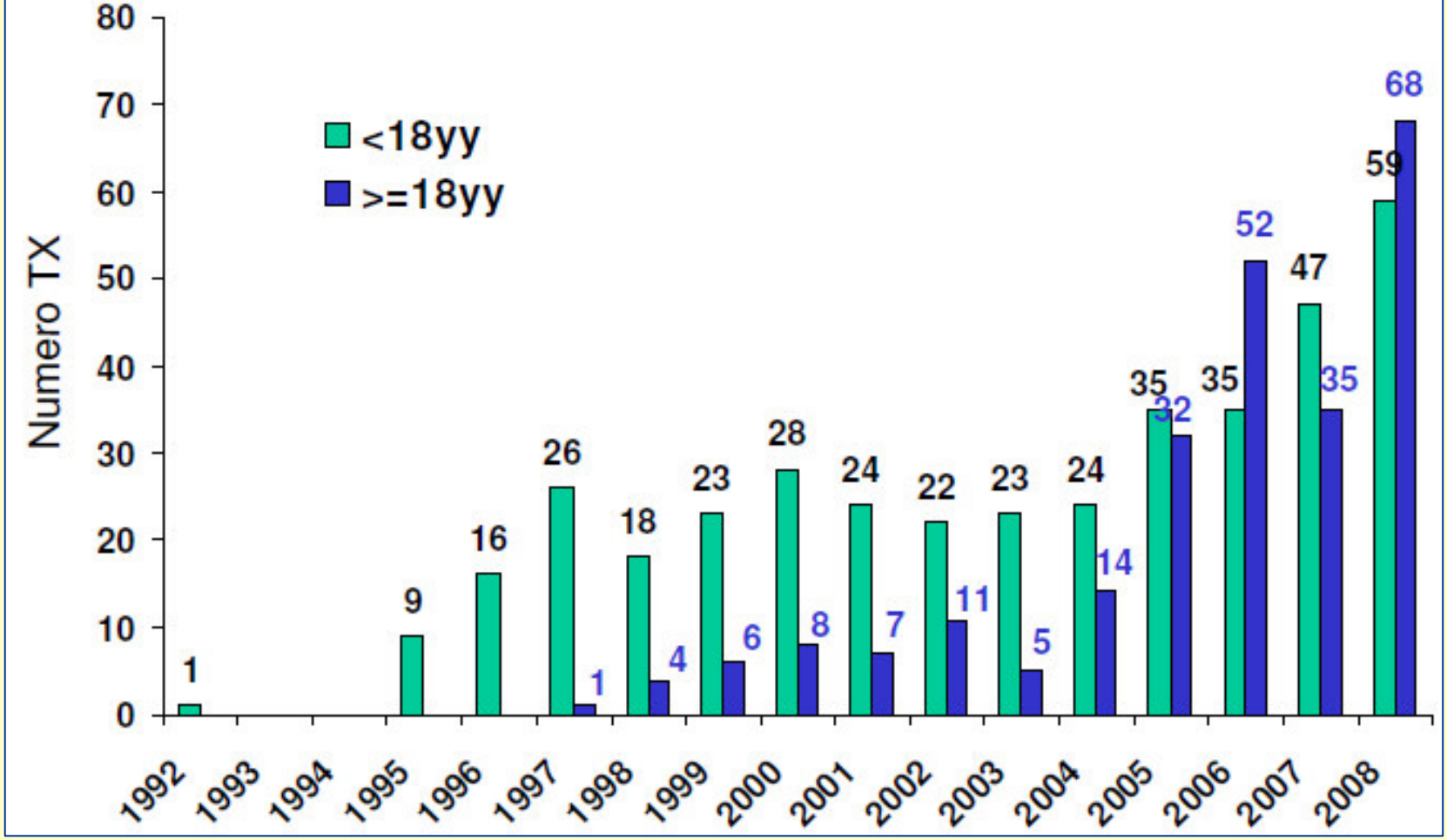
GITMO ONLUS

GITMO ONLUS

Gruppo Italiano per il Trapianto di Midollo Osseo, cellule staminali emopoietiche e terapia cellulare - ONLUS

Iscr. Registro Reg. Liguria – decr. n. 128 del 10/01/00 – cod. fisc. 95107990101 part. iva 01737920991

Allo - trapianti da Cord Blood eseguiti in ITALIA



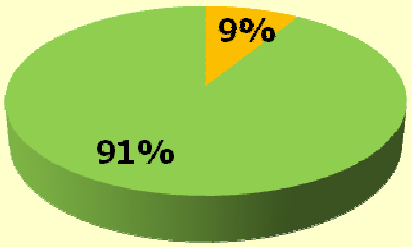
EUROCORD

6756 cord blood transplantations performed from 1988 to March 2010 in 49 countries and **484** transplant centres*

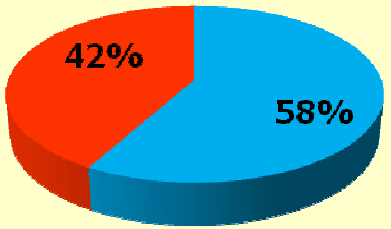
- 264 EBMT — 4847 (73%) cases
- 220 Non-EBMT — 1797 (27%) cases

* missing center in 112 cases

- Related n= 596 (9%)
- Unrelated n=6140 (91%)



- Children n=3875 (58%)
- Adults n=2794 (42%)



Effect of graft source on unrelated donor haemopoietic stem-cell transplantation in adults with acute leukaemia: a retrospective analysis

www.thelancet.com/oncology **Published online June 16, 2010** **DOI:10.1016/S1470-2045(10)70127-3**

Mary Eapen, Vanderson Rocha, Guillermo Sanz, Andromachi Scaradavou, Mei-Jie Zhang, William Arcese, Anne Sirvent, Richard E Champlin, Nelson Chao, Adrian P Gee, Luis Isola, Mary J Laughlin, David I Marks, Samir Nabhan, Annalisa Ruggeri, Robert Soiffer, Mary M Horowitz, Eliane Gluckman, John E Wagner, on behalf of the Center for International Blood and Marrow Transplant Research, the Acute Leukemia Working Party and Eurocord (the European Group for Blood and Marrow Transplantation), and the National Cord Blood Program of the New York Blood Center

- **Interpretation:** "These data support the use of UCB for adults with acute leukaemia
  - → when there is no HLA-matched unrelated adult donor available,
  - → and when a transplant is needed urgently"

Eapen et al, 2010

www.thelancet.com/oncology Published online June 16, 2010 DOI:10.1016/S1470-2045(10)70127-3

	Bone marrow	Peripheral blood progenitor cells	Umbilical-cord blood
Number	472	888	165
Sex (male)	257 (54%)	485 (55%)	83 (50%)
Age (years)			
16–20	69 (15%)	51 (6%)	46 (29%)
21–30	134 (28%)	218 (25%)	44 (26%)
31–40	86 (18%)	202 (23%)	43 (26%)
41–50	105 (22%)	230 (26%)	23 (14%)
>50	78 (17%)	187 (21%)	9 (5%)
Disease			
Acute myeloid leukaemia	276 (58%)	528 (59%)	76 (46%)
Acute lymphoblastic leukaemia	196 (42%)	360 (41%)	89 (54%)
Disease status at transplantation			
First and second complete remission	352 (75%)	618 (70%)	123 (75%)
Relapse	120 (25%)	270 (30%)	42 (25%)

Table 1. **Patient, disease, and transplant characteristics (cont'd →)**

Eapen et al, 2010

www.thelancet.com/oncology Published online June 16, 2010 DOI:10.1016/S1470-2045(10)70127-3

	Bone marrow	Peripheral blood progenitor cells	Umbilical-cord blood
Year of transplant			
2002–04	227 (48%)	323 (36%)	91 (55%)
2005–06	245 (52%)	565 (64%)	74 (45%)
TBI-containing conditioning regimen			
Yes	321 (68%)	583 (66%)	90 (55%)
No	151 (32%)	305 (34%)	75 (45%)
Addition of ATG to conditioning regimen	131 (28%)	161 (18%)	119 (72%)
A, B, C, DRB1 (allele-level)			
Matched (8/8)	332 (70%)	632 (71%)	NA
One-locus (allele or antigen) mismatch (7/8)	140 (30%)	256 (29%)	NA
A, B (antigen level), DRB1 (allele level)			
Matched (6/6)	NA	NA	10 (6%)
One-antigen mismatch (5/6)	NA	NA	40 (24%)
Two-antigen mismatch (4/6)	NA	NA	115 (70%)

Data are n (%). Cord-blood cell dose pre-freeze: 3·6 (range 2·5–9·3)×10^7/kg. Cord-blood cell dose infused: 2·6 (range 1·0–6·1)×10^7/kg. NA=not applicable. TBI=total body irradiation. ATG=anti-thymocyte globulin.

Table 1: **Patient, disease, and transplant characteristics**

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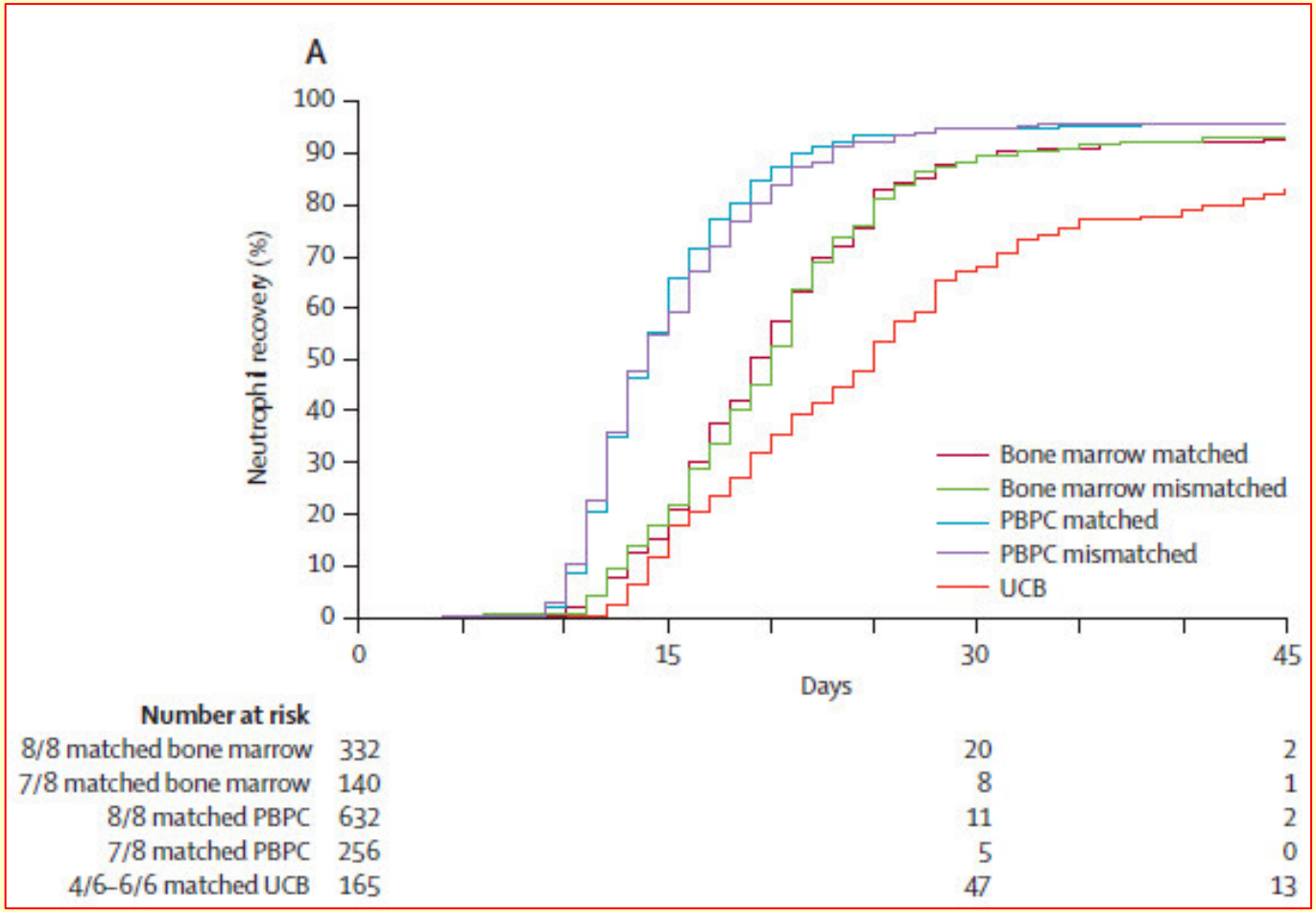

Number at risk			
8/8 matched bone marrow	332	20	2
7/8 matched bone marrow	140	8	1
8/8 matched PBPC	632	11	2
7/8 matched PBPC	256	5	0
4/6–6/6 matched UCB	165	47	13

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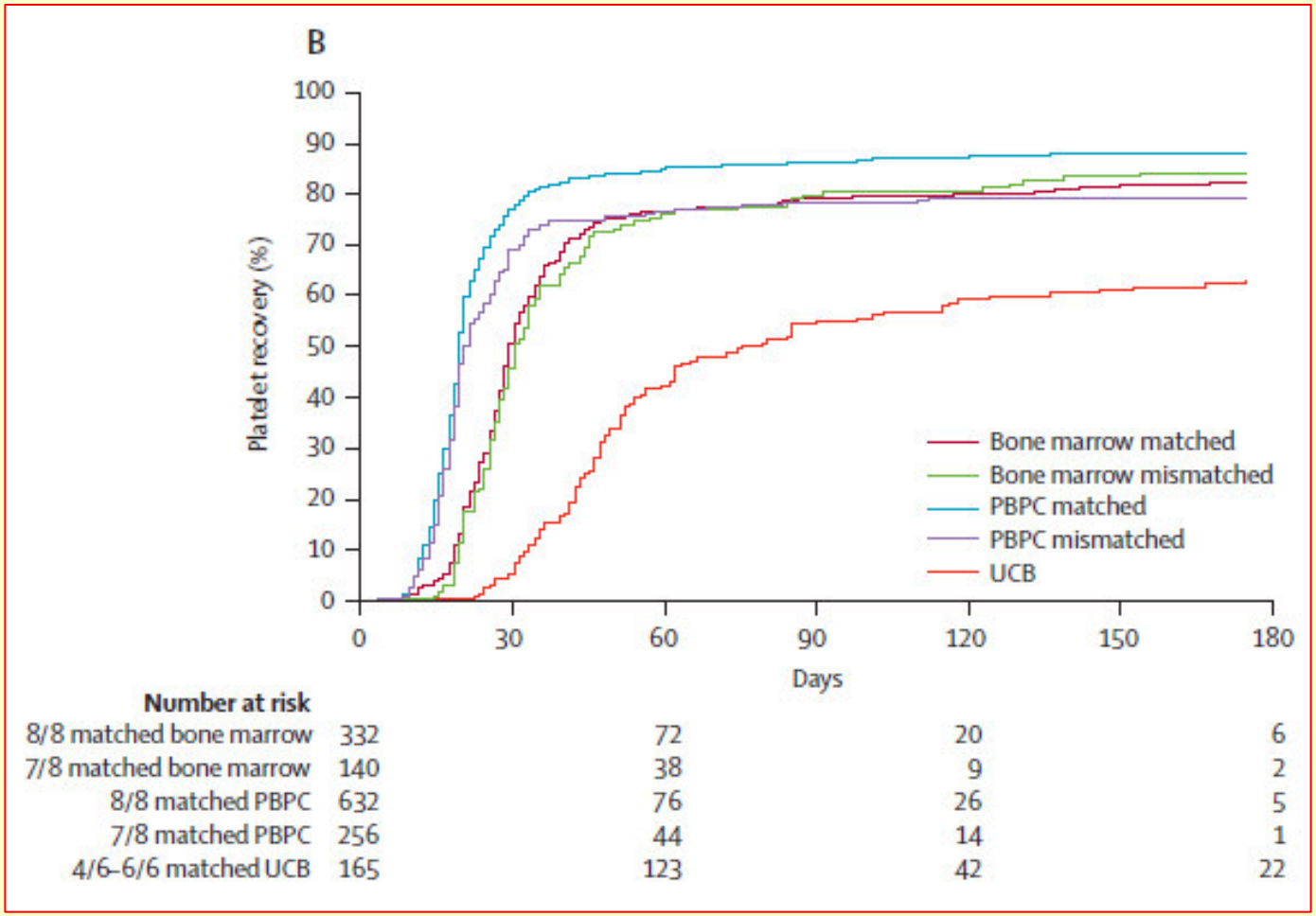

Number at risk				
8/8 matched bone marrow	332	72	20	6
7/8 matched bone marrow	140	38	9	2
8/8 matched PBPC	632	76	26	5
7/8 matched PBPC	256	44	14	1
4/6–6/6 matched UCB	165	123	42	22

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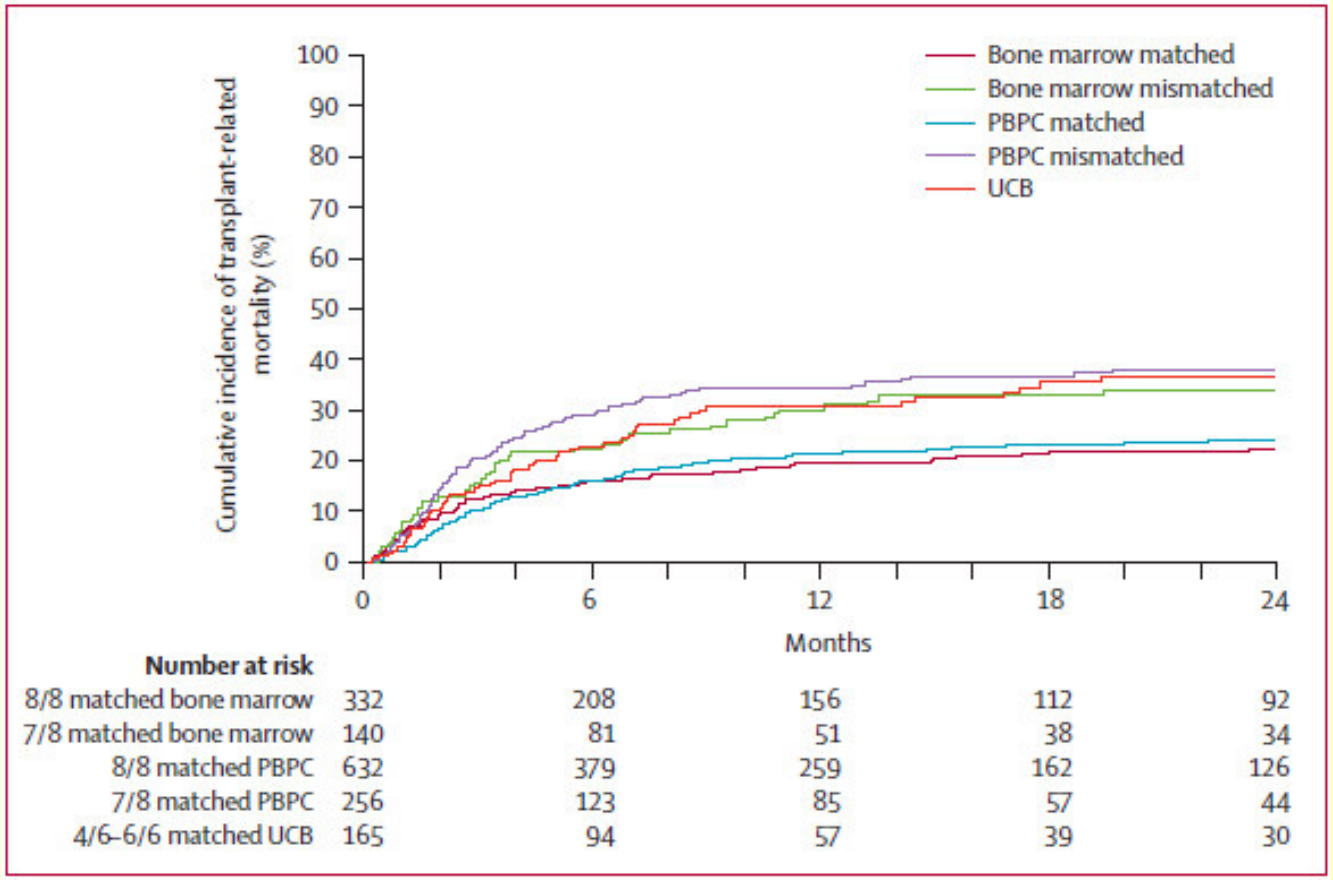

Number at risk					
8/8 matched bone marrow	332	208	156	112	92
7/8 matched bone marrow	140	81	51	38	34
8/8 matched PBPC	632	379	259	162	126
7/8 matched PBPC	256	123	85	57	44
4/6–6/6 matched UCB	165	94	57	39	30

***Figure 2*: The probabilities of transplant-related mortality by haemopoietic stem-cell source and donor-recipient HLA matching**

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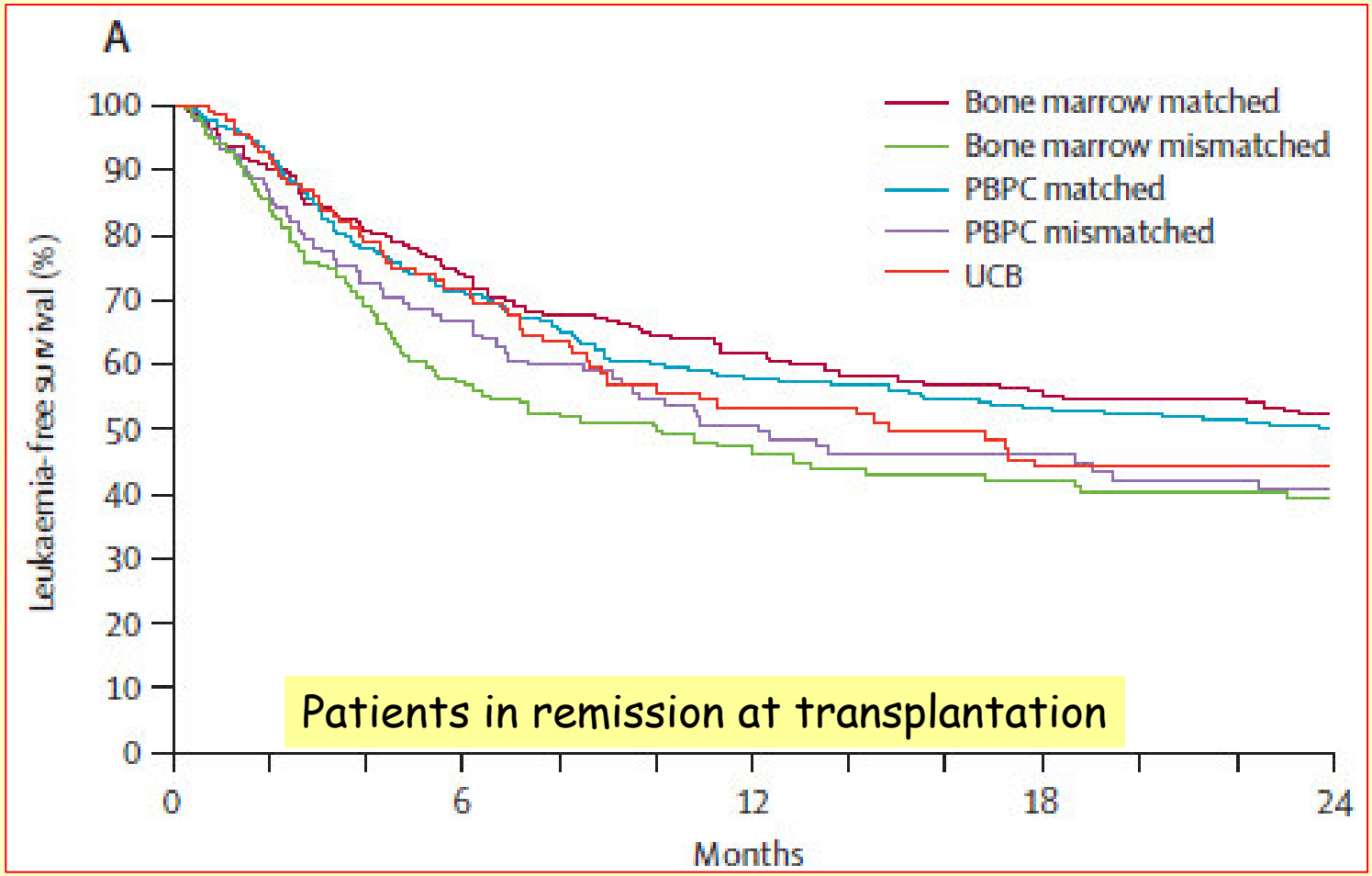

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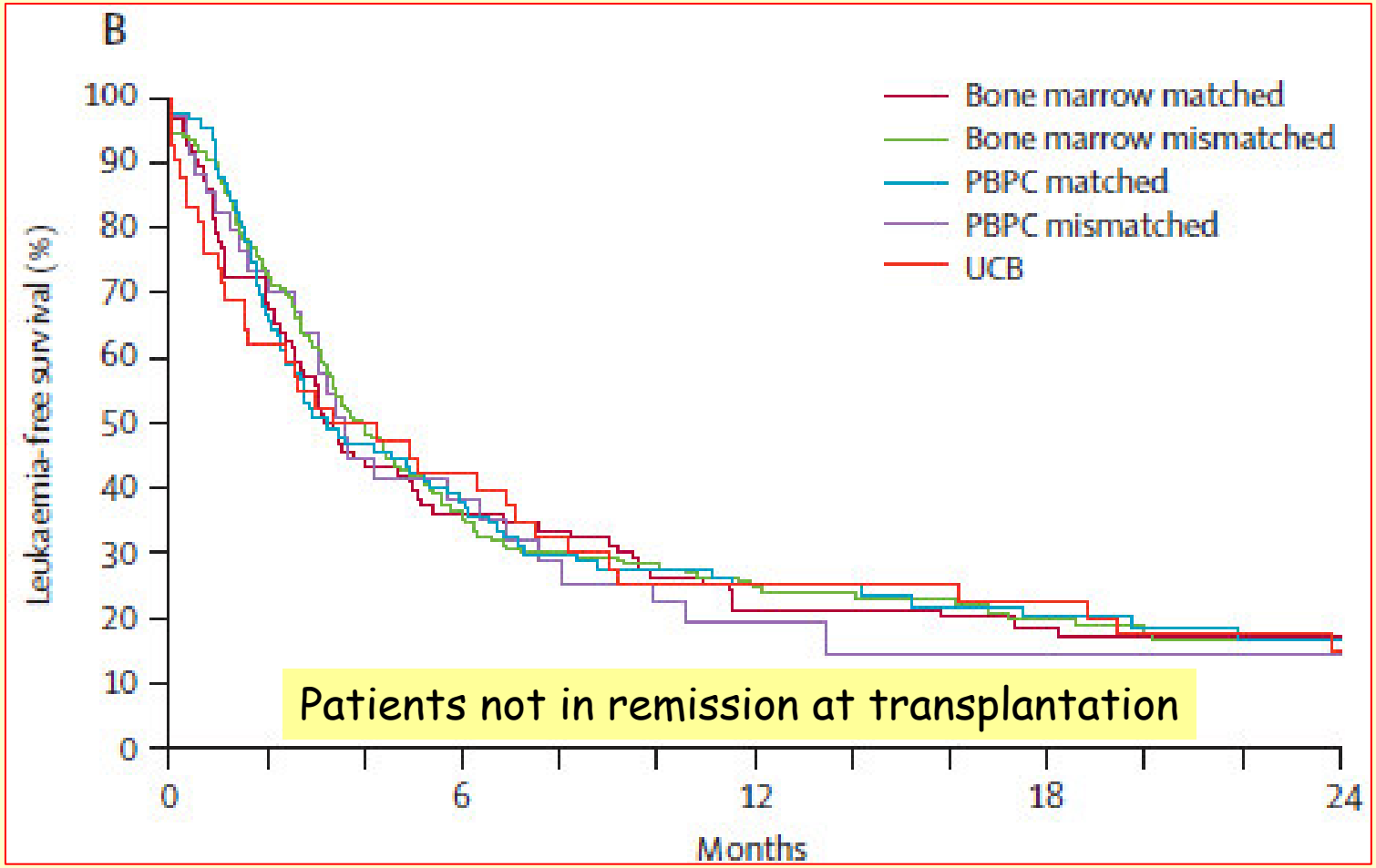

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	Bone marrow	Peripheral-blood progenitor cells	Umbilical-cord blood
Total number	95	180	37
Recurrent leukaemia	25 (26%)	56 (31%)	11 (30%)
EBV-associated lymphoma	NA	1 (<1%)	1 (3%)
Graft versus host disease	8 (8%)	35 (19%)	3 (8%)
Interstitial pneumonitis	9 (9%)	11 (6%)	2 (5%)
Infection	21 (22%)	30 (17%)	10 (27%)
Organ failure	31 (33%)	47 (26%)	10 (27%)
Other	1 (2%)	1 (<1%)	NA

Data are n (%). EBV=Epstein-Barr virus. NA=not applicable.

Table 3: **Early causes of death (within 100 days after transplantation)**

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	Bone marrow	Peripheral-blood progenitor cells	Umbilical-cord blood
Total number	157	308	59
Recurrent leukaemia	105 (67%)	192 (62%)	31 (53%)
EBV-associated lymphoma	1 (<1%)	1 (<1%)	2 (3%)
Graft-versus-host disease	13 (8%)	28 (9%)	12 (20%)
Interstitial pneumonitis	5 (3%)	12 (4%)	1 (2%)
Infection	19 (12%)	39 (13%)	7 (12%)
Organ failure	12 (8%)	35 (11%)	6 (10%)
Other	2 (1%)	1 (<1%)	NA

Data are n (%). EBV=Epstein-Barr virus. NA=not applicable.

Table 4: **Late causes of death (more than 100 days after transplantation)**

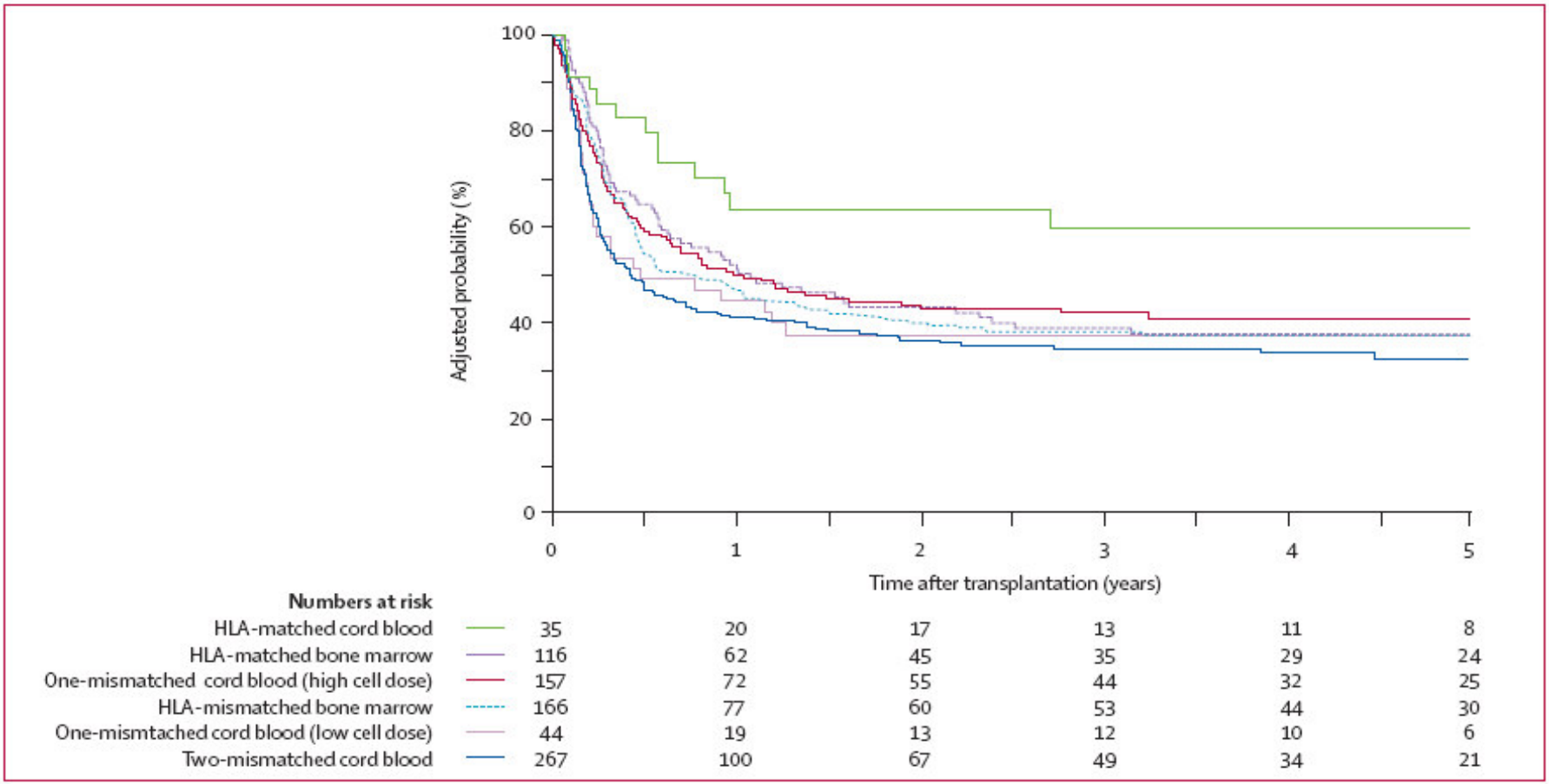
Criteria of donor choice Recommendations 2009

1. **First look at the number of cells in MAC, RIC, single and double CBT :**
   $\geq 2.5 \times 10^7$ NC/kg and or $\geq 1.5 \times 10^5$ CD34+/kg
   Infused $> 2.0 \times 10^7$ NC/kg

2. **Second look at HLA matches**
   - **0-1 mm better than 2 avoid 3-4 mm**
   - **Prefer class I mismatches than class II (does not matter in advanced phase of disease?)**
   - **If no choice increase the number of cells**
   - **It seems that in double CBT number of HLA disparities and ABO compatibility is also important**

3. **Then adapt to graft indication**
   - **Malignant diseases: cell dose is the best prognostic factor because HLA differences reduce relapse (GVL)**
   - **Non malignant diseases: increase cell dose ($\geq 4.0 \times 10^7$ NC/kg) and find the best HLA match.**
   - **Search for antibodies against HLA**

Increase the worldwide CB inventory!



Numbers at risk						
HLA-matched cord blood	35	20	17	13	11	8
HLA-matched bone marrow	116	62	45	35	29	24
One-mismatched cord blood (high cell dose)	157	72	55	44	32	25
HLA-mismatched bone marrow	166	77	60	53	44	30
One-mismtached cord blood (low cell dose)	44	19	13	12	10	6
Two-mismatched cord blood	267	100	67	49	34	21

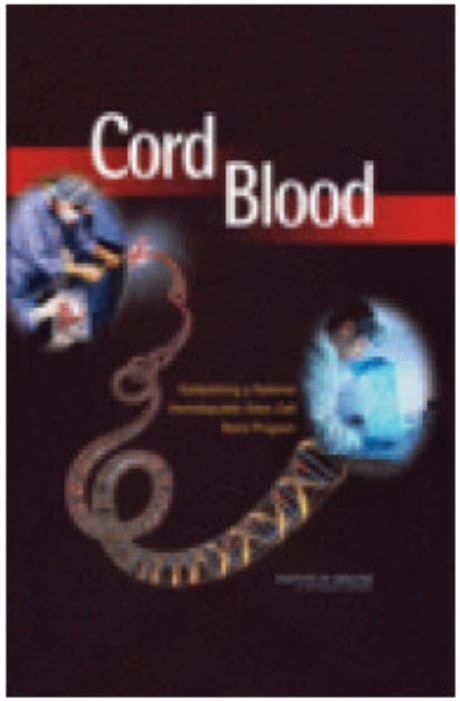
Figure: **Probability of leukaemia-free survival after bone-marrow and cord-blood transplantation adjusted for disease status at transplantation**

Eapen et al, Lancet 2007

Interpretation These data support the use of HLA-matched and one- or two-antigen HLA-mismatched umbilical cord blood in children with acute leukaemia who need transplantation. Because better HLA matching and higher cell doses significantly decrease the risk of transplant-related mortality after umbilical-cord-blood transplantation, greater investment in large-scale banking is needed to increase HLA diversity.

Cord Blood: Establishing a National Hematopoietic Stem Cell Bank Program (Free Executive Summary)
http://www.nap.edu/catalog/11269.html

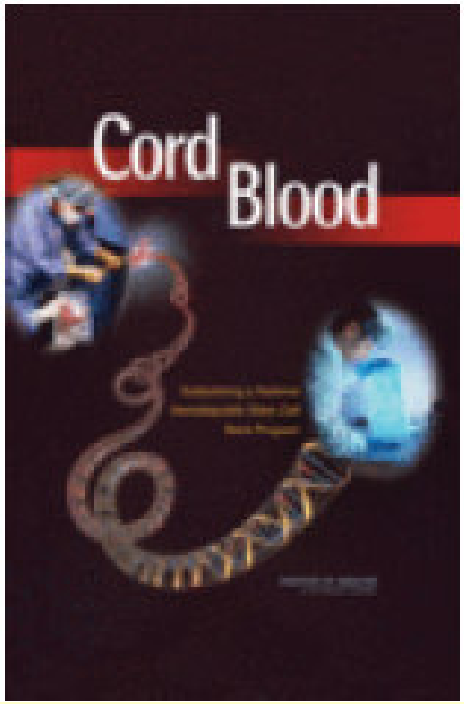
Free Executive Summary



Cord Blood: Establishing a National Hematopoietic Stem Cell Bank Program

Committee on Establishing a National Cord Blood Stem Cell Bank Program, Emily Ann Meyer, Kathi Hanna, and Kristine Gebbie, Editors

ISBN: 0-309-09586-7, 334 pages, 6 x 9, hardback (2005)



http://www.nap.edu

BOX ES-1
Summary of Recommendations for Establishing a National Cord Blood Stem Cell Bank Program

Research

Develop a mechanism to make nonclinical units available for research use (Recommendation 3.1).

Umbilical Cord Blood Banks and Banking

Establish a cord blood accrediting organization (Recommendation 4.1).
Establish uniform standards for cord blood collection (Recommendation 4.2).
Establish uniform quality assurance systems (Recommendation 4.3).
Establish FDA Licensure of Cord Blood Units (Recommendation 4.4).
Quality standards should apply to both public and private banks (Recommendation 4.5).

Ethical and Legal Issues

Cord blood centers need policies regarding who must provide consent (Recommendation 5.1).
Informed consent should be obtained prior to labor and delivery (Recommendation 5.2).
Donors Must Be Provided with Clear Information about their Options (Recommendation 5.3).
Promote the security of medical information (Recommendation 5.4).
Cord blood donors must understand the limitation of their rights (Recommendation 5.5).

Inventory of a National Cord Blood Stem Cell Bank Program

Establish a national inventory policy (Recommendation 6.1).
Continue to conduct outcomes research (Recommendation 6.2).
Expand the current inventory (Recommendation 6.3).

Recommended Structure of a National Program

Establish a National Cord Blood Policy Board (Recommendation 7.1).
Establish a National Cord Blood Coordinating Center (Recommendation 7.2).
Develop an outcomes database for *all* sources of hematopoietic progenitor cells (Recommendation 7.3).
Fund banks to promote inventory growth (Recommendation 7.4).
Financially support infrastructure development (Recommendation 7.5).
Establish criteria for data sharing (Recommendation 7.6).

Cord blood banking policy issues

- 'New' cells for new indications?
- One vs multiple aliquots?
- What volume reduction?
- Overwrapping, vapour storage?
- Double transplant → value of 'small' units?
- Pay per unit or pay per patient?
- World inventory size? → minorities needs
- Competition with autologous storage

14 November 2007

- The American Medical Association voted to encourage mothers wishing to donate cord blood to give the blood to **public cord blood banks**.

- The American Medical Association's new ethical guidelines said doctors will ideally obtain their patient's consent to donate the baby's cord blood **before** the mother goes into labor.

- Doctors should also disclose **any ties** they have to a cord blood bank, the guidelines said.

- Further, doctors should **never accept fees** for a referral to a cord blood bank, the association said.

Pediatrics Group Recommends Public Cord Blood Banking

Bridget M. Kuehn

EXPECTANT PARENTS ARE FACED WITH weighing competing offers to bank their child's cord blood with a for-profit company as "biological insurance" for future family use or with public cord blood banks that make donated cord blood available to seriously ill children and adults who may benefit from cord blood transplantation. To help clarify the facts and aid physicians as they counsel expectant parents regarding these options, the American Academy of Pediatrics has issued a revised policy on cord blood banking (*Pediatrics*. 2007;119:165-170).

The policy encourages parents to donate their newborn's cord blood to public cord banks, where it can be made available to those most in need. It discourages most parents from using private cord blood banks, which can cost thousands of dollars, noting that the chances of a child ever needing their own cord blood are very small—with estimates ranging from 1 in 1000 to 1 in 200 000. However, private cord blood banking is recommended for parents who have an older child with a disorder such as a genetic immune deficiency that might be treated with a transplant of cord blood stem cells.

"Private cord blood banks target parents at an emotionally vulnerable time when the reality is most conditions that might be helped by cord blood stem cells already exist in the infant's cord blood," according to a statement from the academy.

The umbilical cord is typically discarded after birth. However, stem cells contained in cord blood have been shown to be useful for treating some disorders of the blood and immune system as well as certain cancers, according to the March of Dimes. Cord blood is used to treat many disorders that can also be treated by bone marrow transplantation, but has some advantages over bone marrow such as being easier to collect and less likely to be rejected by the recipient. More than 5500 unrelated cord blood stem cell transplants have been completed so far, according to the Academy, and the 1-year survival rate for such transplant is 40% to 80%. Transplants of cord blood stem cells from

James King-Holmes/www.sciencesource.com

The American Academy of Pediatrics' revised policy on cord blood banking encourages most parents to donate their newborn's cord blood to public cord blood banks.

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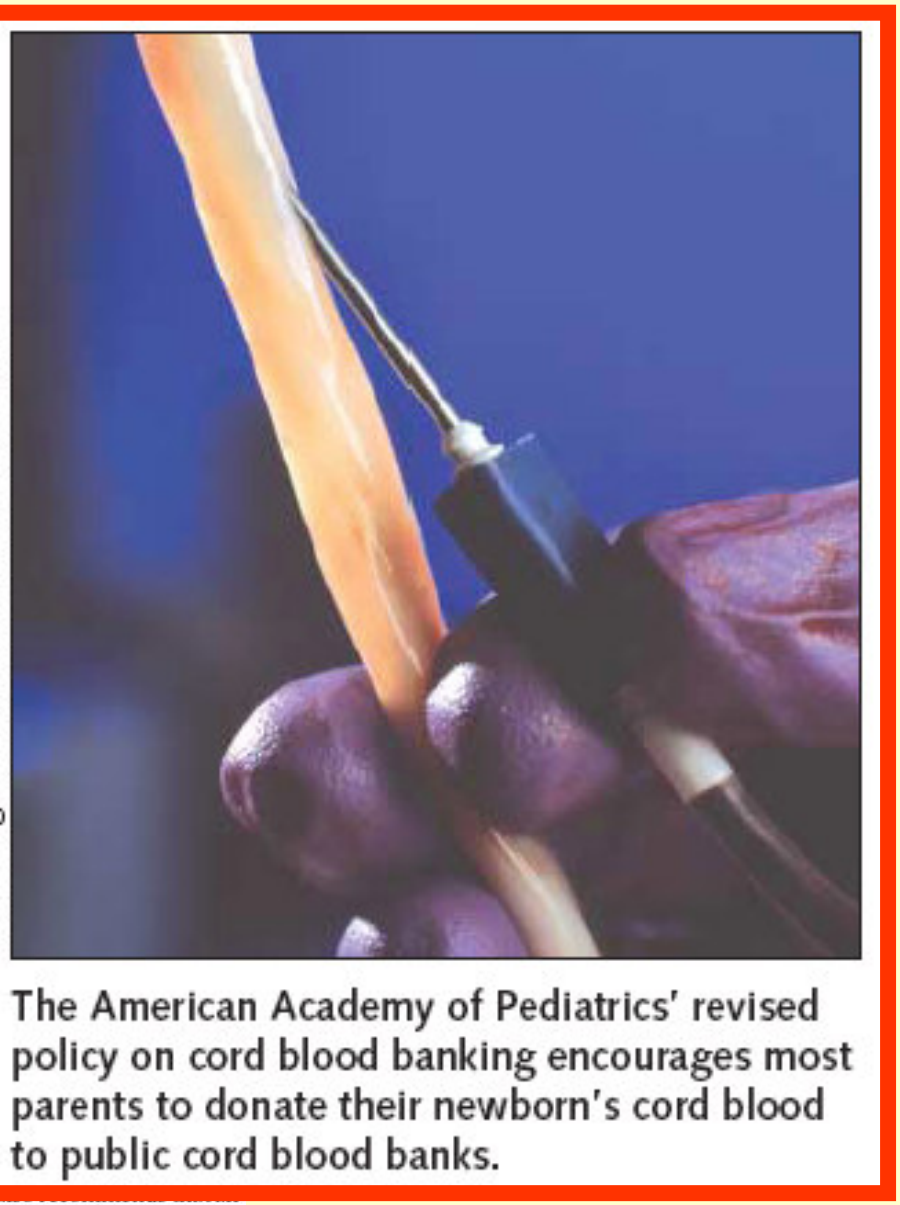

James King-Holmes/www.sciencesource.com

The American Academy of Pediatrics' revised policy on cord blood banking encourages most parents to donate their newborn's cord blood to public cord blood banks.

M.J. Sullivan.
Banking of Cord Blood Stem Cells
Nature Reviews Cancer
July 2008

Clinical indications for allo vs auto CB transplant

Table 1 | **Indications for haematopoietic stem cell transplantation**

Disease	AlloSCT	AlloCB	AutoSCT	AutoCB	Comment
Leukaemia and lymphoma					
ALL; standard and high-risk	N	N	N	N	
ALL; very high-risk and relapse	Y	Y	N	N	Clinical trial-based therapy. AutoCB not indicated
AML; standard-risk	N	N	N	N	
AML; high-risk and relapse	Y	Y	N	N	Clinical trial-based therapy. AutoCB not indicated
AML; secondary (treatment-related)	Y	Y	N	N	
JMML	Y	Y	N	N	
CML; standard-risk	N	N	N	N	
CML; relapsed	Y	Y	N	N	
CLL	Y	Y	N	N	
HD; low stages, localized relapse	N	N	N	N	
HD; advanced-stage, relapse	Y	Y	Y	N/Y	AutoSCT indicated, no advantage for autoCB
NHL; (B and T cell) all stages	N	N	N	N	
NHL; relapsed	Y	Y	Y	N/Y	AlloSCT and autoSCT indicated, no advantage for autoCB
Myeloproliferative disorders					
MDS and refractory anaemia	Y	Y	N	N	
Other myeloproliferative disorders	Y	Y	N	N	
Multiple myeloma	Y	Y	Y	N/Y	AlloSCT and autoSCT indicated, no advantage to autoCB
Lymphohistiocytic disorders					
LCH, standard risk	N	N	N	N	
LCH, relapsed	Y	Y	N	N	
HLH	Y	Y	N	N	
Bone marrow failure					
Aplastic anaemia, congenital	Y	Y	N	N	
Aplastic anaemia, mild, moderate	N	N	N	N	Immunotherapy more effective than SCT
Aplastic anaemia, severe	Y	Y	N	N/Y	AutoCB indicated in the absence of alloSCT or alloCB donor
Fanconi anaemia	Y	Y	N	N	
Congenital anaemias	Y	Y	N	N	
Childhood solid tumours					
Ewing sarcoma	N	N	Y	N	AutoSCT only in clinical trials
Medulloblastoma, standard risk	N	N	N	N	
Medulloblastoma, high-risk	N	N	Y	N	AutoSCT only in clinical trials
Neuroblastoma, stage 1–2	N	N	N	N	
Neuroblastoma, stage 3–4	N	N	Y	Y	See text, no advantage for autoCB compared with autoSCT
Rhabdomyosarcoma	N	N	N	N	SCT not effective for advanced-stage disease
Wilms tumour	N	N	N	N	AutoSCT for rare high-risk and relapsed disease only
Hepatoblastoma	N	N	N	N	AutoSCT for rare high-risk and relapsed disease only
Retinoblastoma	N	N	N	N	AutoSCT for high-risk relapsed disease only
Adult solid tumours					
Breast cancer, stage 1–3	N	N	N	N	
Breast cancer, advanced-stage	N	N	Y	N	AutoSCT in clinical trials only, see text
RCC low-stage	N	N	N	N	
RCC advanced-stage	N	N	Y	N	AutoSCT only in clinical trials, see text
Testicular cancer	N	N	Y	N	AutoSCT only in clinical trials
Other					
Genetic metabolic disorders	Y	Y	N	N	AlloSCT and AlloCB only
Haemoglobinopathies	Y	Y	N	N	
Immune deficiency syndromes	Y	Y	N	N	

Haemoglobinopathies include sickle cell disease and thalassaemia. Immune deficiencies include chronic granulomatous disease, severe combined immunodeficiency, Chediak–Higashi syndrome, lymphoproliferative disorders and Kostmann syndrome. Other myeloproliferative disorders include myelofibrosis, polycythemia vera or essential thrombocythaemia. ALL, acute lymphoblastic leukaemia; alloCB, allogeneic cord blood stem cell transplantation; alloSCT, related and unrelated allogeneic bone marrow, peripheral blood; AML, acute myeloid leukaemia; autoCB, autologous cord blood transplantation; autoSCT, autologous bone marrow and peripheral blood stem cell transplantation; CLL, chronic lymphocytic leukaemia; CML, chronic myeloid leukaemia; HD, Hodgkin disease; HLH, haemophagiocytic lymphohistiocytosis; LCH, Langerhans cell histiocytosis; JMML, juvenile myelomonocytic leukaemia; MDS, myelodysplastic syndrome; NHL, non-Hodgkin lymphoma; RCC, renal cell carcinoma.

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Private cord blood banking: experiences and views of pediatric hematopoietic cell transplantation physicians.

Thornley I, Eapen M, Sung L, Lee SJ, Davies SM, Joffe S.

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OBJECTIVE: Private cord blood banks are for-profit companies that facilitate storage of umbilical cord blood for personal or family use. Pediatric hematopoietic cell transplantation physicians are currently best situated to use cord blood therapeutically. We sought to describe the experiences and views of these physicians regarding private cord blood banking.

PARTICIPANTS AND METHODS: We e-mailed a cross-sectional survey to pediatric hematopoietic cell transplantation physicians in the United States and Canada; 93 of 152 potentially eligible physicians (93 of 130 confirmed survey recipients) from 57 centers responded. Questions addressed the number of transplants performed by using privately banked cord blood, willingness to use banked autologous cord blood in specific clinical settings, and recommendations to parents regarding private cord blood banking.

RESULTS: Respondents reported having performed 9 autologous and 41 allogeneic transplants using privately banked cord blood. In 36 of 40 allogeneic cases for which data were available, the cord blood had been collected because of a known indication in the recipient. Few respondents would choose autologous cord blood over alternative stem cell sources for treatment of acute lymphoblastic leukemia in second remission. In contrast, 55% would choose autologous cord blood to treat high-risk neuroblastoma, or to treat severe aplastic anemia in the absence of an available sibling donor. No respondent would recommend private cord blood banking for a newborn with 1 healthy sibling when both parents were of northern European descent; 11% would recommend banking when parents were of different minority ethnicities.

CONCLUSIONS: Few transplants have been performed by using cord blood stored in the absence of a known indication in the recipient. Willingness to use banked autologous cord blood varies depending on disease and availability of alternative stem cell sources. **Few pediatric hematopoietic cell transplantation physicians endorse private cord blood banking in the absence of an identified recipient, even for mixed-ethnicity children for whom finding a suitably matched unrelated donor may be difficult.**

Autologous storage

Communication

Cell Stem Cell

Correspondence

Stem Cell Clinics Online: The Direct-to-Consumer Portrayal of Stem Cell Medicine

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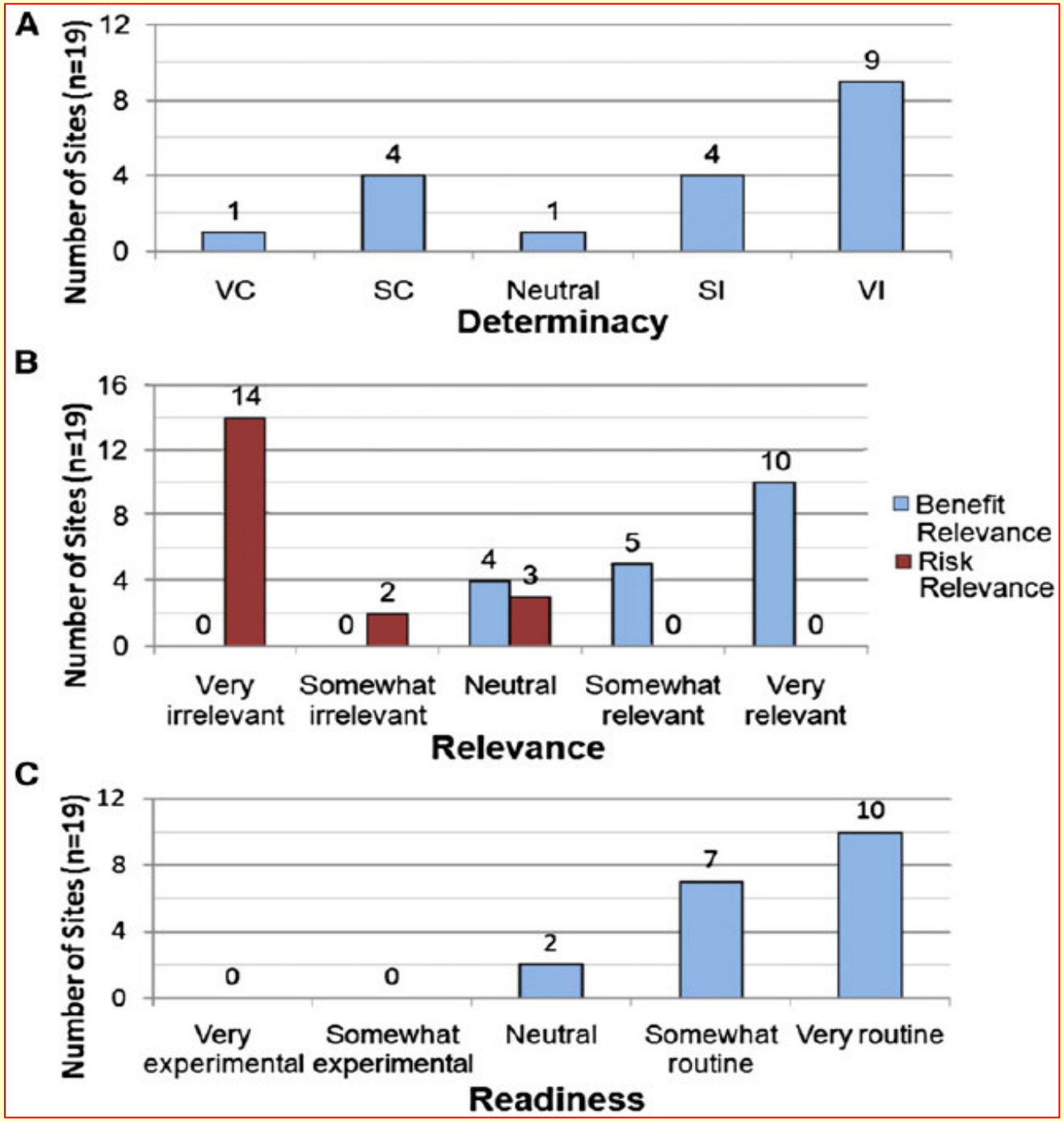

bjh review

Cord blood banking: 'providing cord blood banking for a nation'

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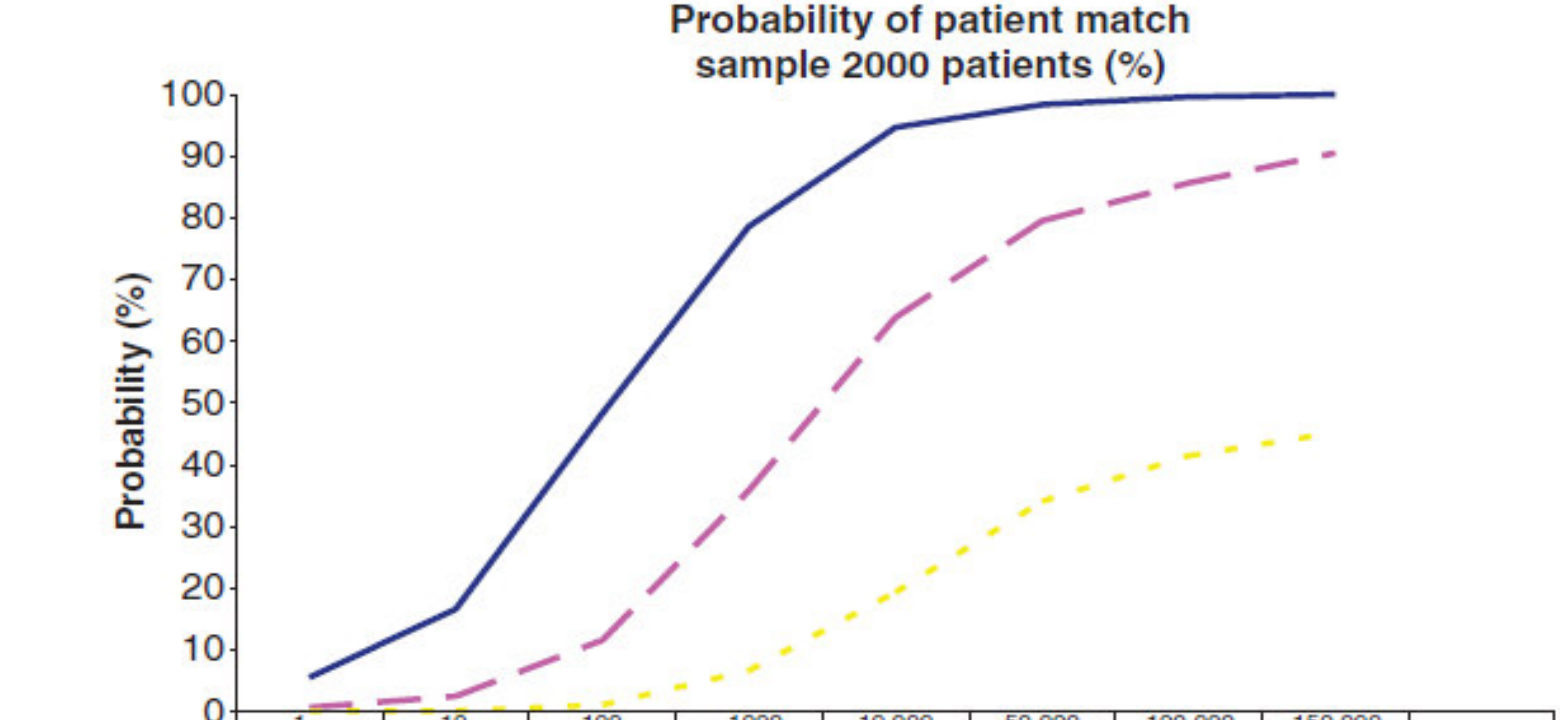


	1	10	100	1000	10 000	50 000	100 000	150 000	
Match 4 of 6	5·5	16·5	48·25	78·5	94·6	98·25	99·55	99·9	
Match 5 of 6	0·65	2·45	11·5	35·75	63·8	79·5	85·55	90·45	
Match 6 of 6	0	0·05	1	6·55	19·25	34·05	41·35	45·15	

Fig 3. Prediction of the percentage of patients requesting a donor (2000 consecutive patients) at the Anthony Nolan Register finding at least one donor for each predefined donor size inventory according to match categories

My answers for (future) Italian CB banking

- Italian needs?
  - Autologous? Undemonstrated benefits
  - Allogeneic (solidaristic)?
  - → **50,000-100,000 allogeneic units**
  - → **Related units for proven indications**
  - Mixed (auto/allo)? Does not work

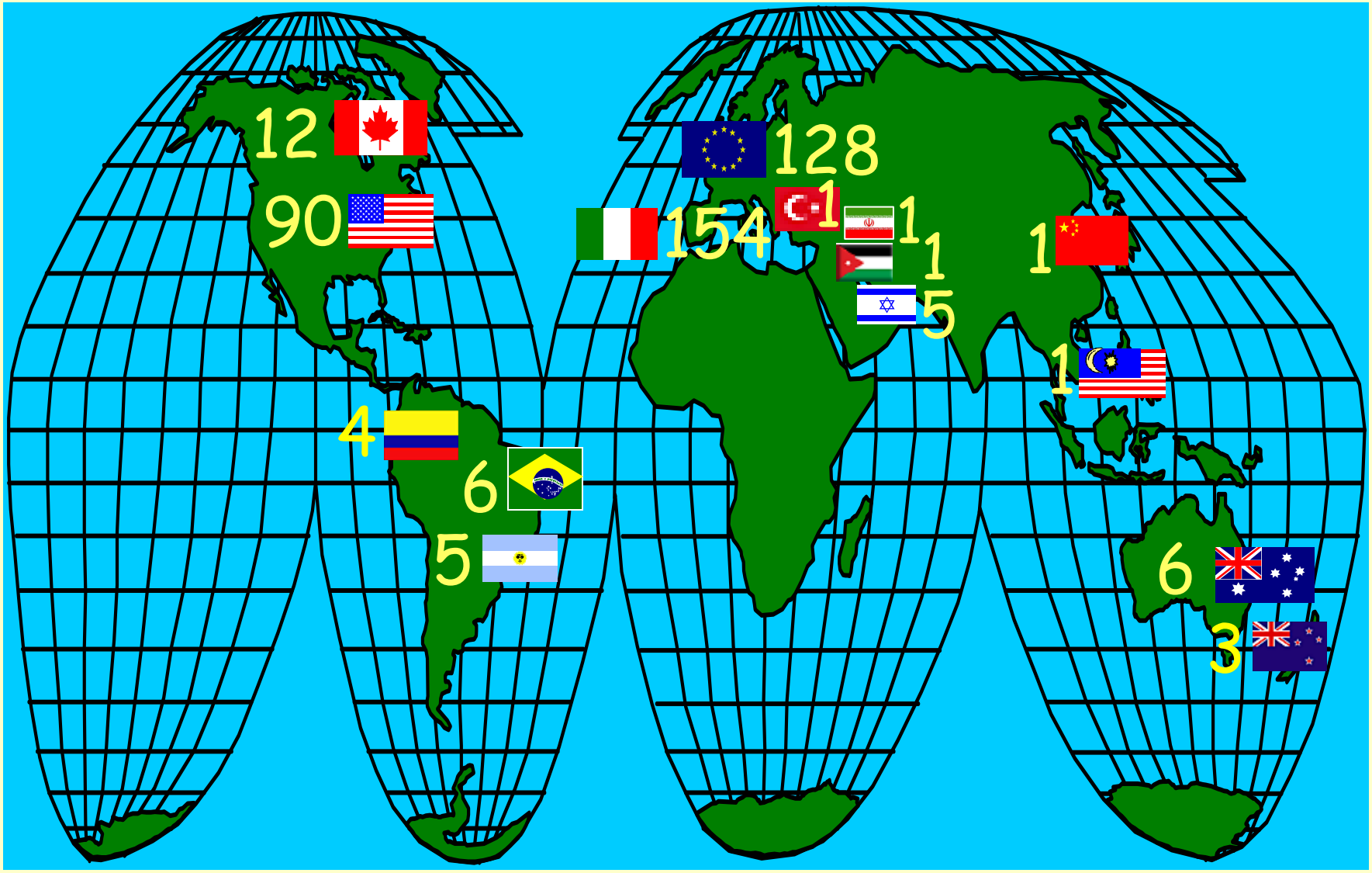
A social and political issue

- Pay per CB unit?
- Pay per transplanted patient?

Advantages of 'pay per patient' vs 'pay per unit' policy…

- Facilitation of cord blood transplant by avoiding 'discriminatory' costs for double transplants
- Increase of CB bank cost recovery by increasing no. of distributed units

Milano Cord Blood Bank
418 units released for unrelated cord blood transplant during 1995-2009



Our appreciation and gratitude go to:

- ✓ 24,304 mothers who donated their babies' cord bloods to the Milano Cord Blood Bank,
- ✓ 709 trained midwives and gyn's who collected them,
- ✓ MICB staff who banked our 8,526 units
- ✓ 146 transplant teams who transplanted 443 of those units worldwide during 1993-2010.

➔ Our target is to triplicate our inventory with larger cell doses and increase the current 40% K-M disease-free survival rate of recipients of MICB units.