

La necesidad de acreditarse en México

**Experiencia del Banco de Sangre de
Cordón Umbilical del
Banco Central de Sangre del Centro
Médico Nacional La Raza
Instituto Mexicano del Seguro Social**

Dra. Bárbara Novelo Garza

Antecedentes

- **Febrero de 1961 cuando en la revista *Radiation Research* existencia de la célula progenitora.**
- **El primer trasplante que se realiza de CPH de M.O. fue por el Dr. Georges Mathé en 1958.**
- **El Dr. E. Donnall Thomas en la década de los 60 y 70 realiza en forma sistemática el trasplante de CPH, llevándolo al previo Nobel de Medicina en 1990.**
- **Gracias a la producción de Concentrados Plaquetarios, antibióticos y medicamentos anti neoplásicos crece el trasplante de CPH en forma espectacular en los 80 y 90.**
- **Para 1988 se realiza el primer trasplante de CPH de origen de sangre de cordón umbilical.**

Orígenes del BSCU del CMN

La Raza

- **Gracias a la invitación del Dr. Héctor Mayani jefe de la Unidad de Investigación del H. de Oncología del CMN SXXI en formar parte del proyecto del Banco de Sangre de Cordón Umbilical.**
- **Se inicia el trabajo en 2002 y surgen varias preguntas**
 - **¿Qué legislación existe?**
 - **¿Cómo me debo organizar?**
 - **¿Lo estoy haciendo bien?**
 - **¿Cómo lo evalúo para ver si lo estoy haciendo bien?**
 - **¿Me va alcanzar el dinero?**
 - **¿Hacia donde quiero ir?**
 - **¿Tengo que documentar todo mi proceso?**
 - **¿EL área de aseguramiento de la calidad me debe de realizar inspecciones del proceso y mostrarme resultados?**
 - **¿Tengo que analizar los resultados?**

Las preguntas anteriores se contestaron al implantar un sistema de gestión de calidad

Nos llevó desde el 2002 al 2005 abrir con todo el proceso estandarizado

Promoción



Contar con mecanismo de difusión al personal promotor del programa de donación de sangre de cordón umbilical en las unidades médicas del Instituto Mexicano del Seguro Social

Selección de Donadoras

SELECCION DE DONADORAS ALTRUISTAS

GRUPOS DE EDAD:
18 a 30 años 73%
31 a 40 años 26%
41 o más 1%

EMBARAZOS:
G I 31%
G II 40%
G III 19%
G IV 10%



Recolección



SEMANAS DE GESTACIÓN

34 a 37
semanas 11%

38 a 42
semanas 89%

VÍA DE OBTENCIÓN

Vaginal 67%

Cesárea 33%

Procesamiento



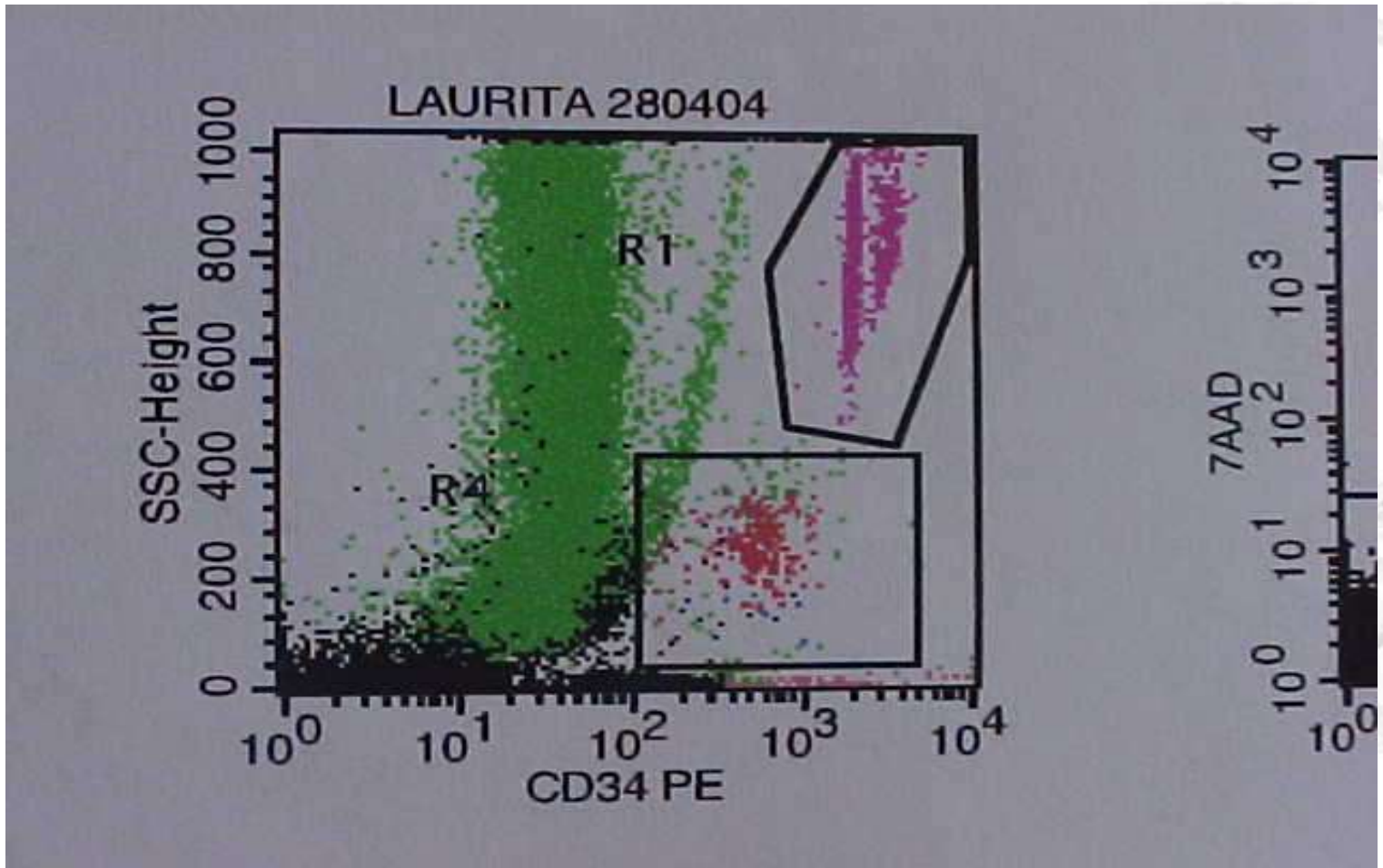
**CUENTA
INICIAL DE
CNT
8 X 10⁶**

**REDUCCIÓN
DE
VOLUMEN
20 ml ± 2
ml**

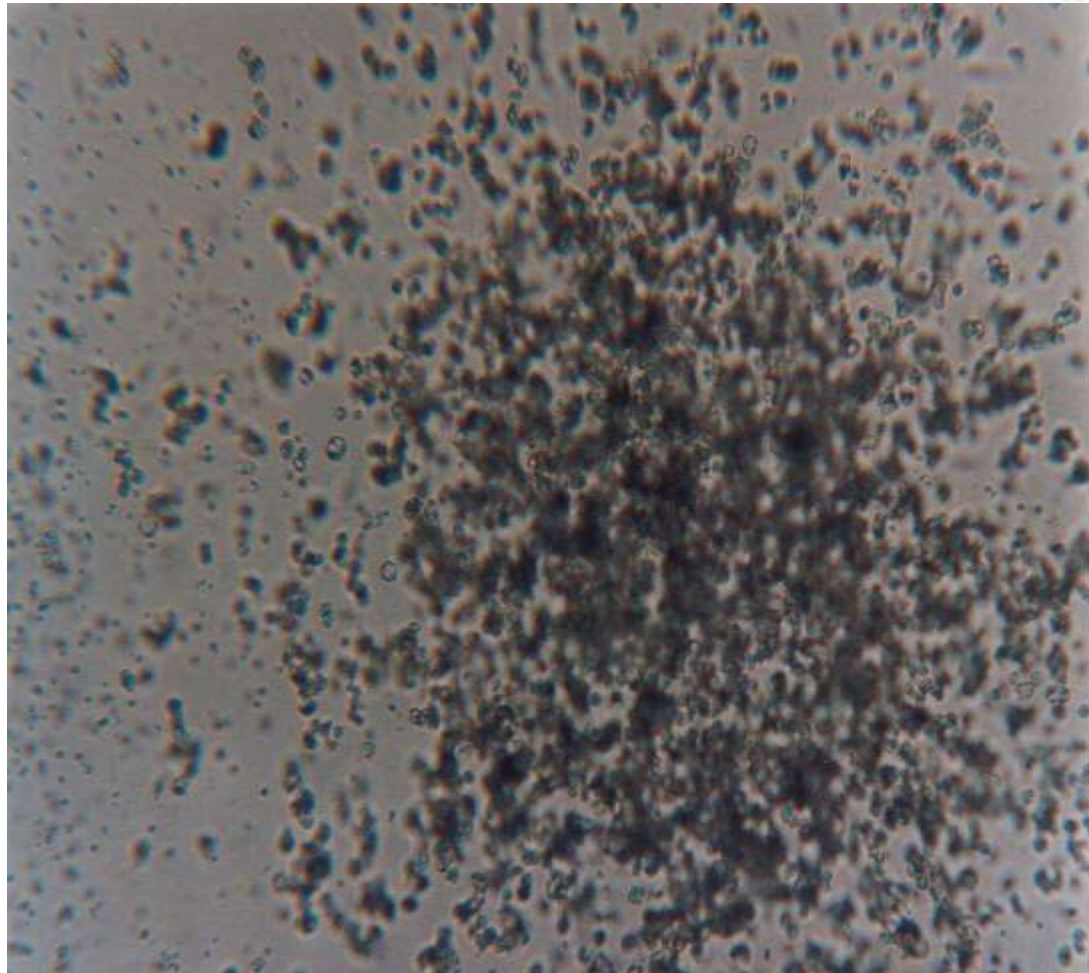
**ESTUDIO DE
HLA
SSP**

DNA TECA

Citometría de Flujo



Cultivos Clonogénicos



Almacenamiento



Almacenamiento
en
el sistema de
Bioarchivo
Thermogenesis

Almacenamiento

A faint, stylized map of the Americas, showing the outlines of North and South America, positioned behind the text.

Criopreservación

Entrega de la Unidad

A faint, semi-transparent globe of the Earth is positioned in the background on the right side of the slide.

Selección de
la
unidad útil
para
el paciente

Trasplante





Quality
Endorsed
Company

CERTIFICATE OF REGISTRATION

Instituto Mexicano del Seguro Social / Banco Central de Sangre del Centro Médico Nacional 'La Raza'

Jacarandas y Seris S/N Colonia "La Raza", Delegación Azcapotzalco, Distrito Federal,
México, C.P. 02990 MEXICO

complies with the requirements of

ISO 9001:2000

Exclusions: Design and Development
Quality Management Systems - Requirements

for the following capability

La Certificación cubre el Sistema de Gestión de la Calidad para el proceso de la Información y
Promoción de la Donación de Sangre de Cordón Umbilical, su colección, procesamiento,
almacenamiento y entrega de Células Progenitoras Hematopoyéticas.

This Registration Covers the Quality Management System to the Processes of Information and
Promotion of Umbilical Cord Blood Donation, its Collection, Processing, Storing, and Delivery of
Hematopoietic Stem Cells.

Registered by:

SAI Global Certification Services Pty Ltd UACA 108 710 600, 200 Sussex Street Sydney NSW 2000 Australia with SAI Global Inc. ("SAI Global")
and subject to the SAI Global Terms and Conditions for Certification. While all the work and staff was supervised in carrying out the assessment,
SAI Global accepts responsibility only for process compliance. The certificate remains the property of SAI Global and must be returned to SAI
Global upon its request.

Certificate No: QEC15873
Issue Date: 10 April 2006

Certified Date: 10 January 2006
Expiry Date: 10 January 2009

Alex Korachnick
General Manager Certification
for and on behalf of
SAI Global

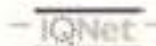
Carl F. Black
Authorized Local Signatory
for and on behalf of
SAI Global



SAI GLOBAL



IAS-ANZ



To verify that this certificate is current please refer to the SAI Global Pty Ltd Certification Register: www.sai-global.com

Sistema de gestión de calidad

El Objetivo de este Boletín es proporcionar información adicional a la que en forma regular obtenemos, además de invitar a todos los que participamos en esta unidad Médica a fortalecerlo, para mayores informes:

EL COMITÉ DE CALIDAD:

Presidente

Dra. Bárbara Novelo Garza

Representante de la Dirección

QFB Judith Navarro Luna

Secretaria

IBQ María del Carmen Villegas Cravioto

Vocales

Lic. Sergio Zárate González

Dr. Ángel Guerra Marquez

Dra. Araceli Malagón Martínez

QFB Luz del Carmen Mávil Lara

Lic.Enf. Guillermina Castañeda Solís

T.S. María de Jesús Pichardo Martínez

Sr. Moisés Mendoza Plata

QBP. Lilia Rodríguez Sánchez

C. Roberto García bautista

Lab. Víctor guerrero Arredondo

BOLETÍN

INFORMATIVO

DEL

BANCO DE SANGRE DE CORDÓN UMBILICAL

Nº. 2,

MARZO

AÑO 2006

GRACIAS AL ESFUERZO DE TODOS NOS CERTIFICAMOS ISO 9001:2000

Los pasados 21 Y 22 de Diciembre del 2005 se llevó a cabo la auditoria para la certificación por parte de Singapore Australian Internacional Inc. (SAI Global, Inc.), auditoria que se supero satisfactoriamente sin tener una sola no conformidad.

El alcance de la certificación cubre todos los procesos de información y promoción de la donación de sangre de cordón umbilical, colección, procesamiento, almacenamiento y entrega de células progenitoras hematopoyéticas.

Es la primera área de la atención médica con trato directo al usuario que establece y certifica su Sistema de Gestión de Calidad (SGC) en el Instituto Mexicano del Seguro Social.

El alcance del SGC en el Banco de Sangre de Cordón Umbilical fue total, por lo que se generaron: 1 manual de calidad, 1 manual de seguridad y 1 manual metodológico de laboratorio, además de 10 procedimientos de calidad, 18 métodos específicos de trabajo y 10 técnicas de procesamiento. Por tal razón califica como el primer SGC de mayor complejidad certificado en el Instituto.

Buscando constituirse como un Banco de Sangre de Cordón Umbilical de "clase mundial", desde que se planeó su creación se decidió implantar en paralelo el SGC con base a normas internacionales como: ISO 9001:2000 y NetCord 2001 (Internacional Standard for Cord Blood Collection, Processing, Testing, Banking, Selección and Release)

El número de certificado es QEC15873 por la Compañía Internacional denominada SAI Global Inc. acreditado por JAS-ANZ (Australia) y ANAB (Estados Unidos), así como el reconocimiento internacional de los miembros de IQnet (Internacional Certification Network) de la Unión Europea. Por lo que la acreditación alcanzada hace que nuestro Sistema de Gestión de Calidad sea reconocido en Asia, Estados Unidos y Europa.

Por otra parte dentro de la Cruzada Nacional por la Calidad de los Servicios Médicos de Salud se llevó a cabo el "IV Foro Nacional por la Calidad en Salud" efectuada el pasado 6,7 y 8 del mes en curso, donde presentamos el trabajo "IMPLEMENTACIÓN DEL SERVICIO DE CÉLULAS PROGENITORAS HEMATOPOYÉTICAS OBTENIDAS DE SANGRE DE CORDON UMBILICAL" quedó aceptado en los 100 trabajos finalistas de todo el país para ser presentado como cartel y además dentro de un panel de discusión.

Actualmente contamos con más de 140 unidades criopreservadas de CPH disponibles para trasplante y para el próximo mes ya se tiene programado el segundo trasplante en el Hospital General del CMN La Raza a un niño con Diagnóstico de Leucemia, la unidad a trasplantar tiene una histocompatibilidad de 6/6 y una buena celularidad por lo que esperamos que sea un éxito

MUCHAS FELICIDADES POR EL ESFUERZO REALIZADO EN BENEFICIO DE NUESTROS PACIENTES

Establishing a cord blood banking and transplantation program in Mexico: a single institution experience

Barbara Novelo-Garza, Alejandro Limón-Flores, Angel Guerra-Marquez, Fernando Luna-Bautista, Luis Juan-Shum, Ines Montero, Elizabeth Sanchez-Valle, María Antonieta Vélez-Ruelas, and Hector Mayani

BACKGROUND: Over the past decade, umbilical cord blood (UCB) banking and transplantation have increased significantly worldwide. The experience in developing countries, however, is still limited. In January 2005 the Mexican Institute of Social Security (IMSS) initiated its UCB banking and transplantation program. This study reports on the experience generated at this institution during the first 2 years of activities.

STUDY DESIGN AND METHODS: A public UCB bank was established at La Raza Medical Center, IMSS, in Mexico City. Good manufacturing practices and standard operating procedures were used to address donor selection, as well as UCB collection, processing, and cryopreservation. Based mainly on human leukocyte antigen (HLA) and total nucleated cell (TNC) content, specific UCB units were thawed, processed, and released for transplantation.

RESULTS: Based on stringent selection criteria, 360 UCB units were collected from January 2005 to December 2006. A total of 201 (56%) units (minimum volume, 50 mL without anticoagulant) were processed and stored. Median values for specific parameters were as follows: volume, 89.9 mL; viability, 94.8%; TNCs, 0.91×10^6 ; CD34⁺ cells, 3.13×10^4 ; and colony-forming cells, 1.20×10^2 . During this period, 10 units had been released for transplantation to seven patients (six children and one adult). Engraftment was observed in five patients; four of them were still in remission (114–293 days after transplant). In spite of showing sustained engraftment, one patient died on Day +88. Two patients showed no engraftment and died 29 to 30 days after transplant.

CONCLUSION: The results obtained during this initial period are encouraging and indicate that the UCB banking and transplantation program at IMSS will help to improve already existing hematopoietic cell transplant programs in Mexico. The experience generated at IMSS may be helpful to other institutions, particularly those in developing countries.

More than 30 years ago it was demonstrated that significant numbers of primitive hematopoietic cells are found in umbilical cord blood (UCB).¹ It was not until the late 1980s, however, that UCB was recognized as a rich source of hematopoietic stem and progenitor cells for potential clinical use.² In keeping with this notion, the first hematopoietic cell transplant in which UCB was used as the source of hematopoietic cells, instead of marrow, was performed in Paris, France, in 1988.³ Over the past 15 years significant advances have been made both in the basic biology of UCB-derived stem and progenitor cells⁴ and in the clinical application of such cells.^{5,6}

ABBREVIATIONS: CBB = Cord Blood Bank; CFU(s) = colony-forming cells; HLA = human leukocyte antigen; IMSS = Mexican Institute of Social Security; TNC(s) = total nucleated cell(s); UCB = umbilical cord blood.

From the Umbilical Cord Blood Bank and the Department of Pediatric Hematology, La Raza Medical Center, IMSS, Mexico City; the Department of Hematology, Medical Specialties Hospital, IMSS, Puebla City; the Department of Hematology, Pediatrics Hospital, the Department of Hematology, Medical Specialties Hospital, and the Oncology Research Unit, Oncology Hospital, Siglo XXI Medical Center, IMSS, Mexico City; and the Department of Pediatrics, Gabriel Mancera Hospital, IMSS, Mexico City, Mexico.

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TRANSFUSION 2008;48:228–236.



Public cord blood banking may play an important role in the emergence of unrelated transplant in developing countries

In this issue of **TRANSFUSION**, Novelo-Garza and colleagues¹ describe the development of a public cord blood bank and transplantation program at the La Raza Medical Center in Mexico City. Although cord blood banking is well established in many countries, the development of cord blood banking in this setting is indeed noteworthy. The article shows that standards that have emerged for cord blood banking elsewhere can be adapted for use in Mexico and suggests that the development of public cord blood banking may provide a viable approach to support the emergence of unrelated transplantation programs in developing countries. Finally, the emergence of high-quality public cord blood banks in developing countries will likely contribute to the greater pool of available cell sources for the benefit of patients around the globe.

Public cord blood banks have become an integral part of the network of organizations that support unrelated cellular transplantation. World Marrow Donor Association (WMDA) data show that the use of cord blood in transplantation is rapidly expanding. At present, 47 cord blood banks from around the world report data to WMDA. In 2006, these banks provided 2086 cord blood units for unrelated transplantation, a growth of 16.5 percent over 2005 and an 85 percent increase over 2004. According to the WMDA, cord blood grafts represented 20 percent of all cell sources provided for unrelated transplantation in 2006. In the United States, the number of cord blood transplants will likely exceed the number of marrow transplants in 2008. At the same time, unrelated transplantation with adult-derived donations continues to grow both in the United States and worldwide.^{2,3} This suggests that cord blood has provided a valuable resource for patients who may not otherwise have found an acceptable adult donation, increasing access to this unrelated transplant therapy as a result.

Recently, unrelated transplantation has emerged as a therapeutic option in Mexico. This development has been supported by the establishment of an adult donor registry in Mexico. Although small, it has successfully provided adult donations for both domestic and international patients. The program of Novelo-Garza and colleagues, and the previously established Mexican Unrelated Cord Blood Bank (BACECU), suggests that the development of

the public cord blood banking may provide a means to significantly expand the development of unrelated transplant in certain settings.

The ability of the La Raza Medical Center to establish a successful cord blood bank is due in large part to the experience of others who pioneered the science of cord blood banking. Led by the groundbreaking work of Pablo Rubenstein and his colleagues at the New York Blood Center and the contribution by many others over the past 15 years, a strong foundation was available to the Mexican Medical Center. Importantly, the group of Novelo-Garza and colleagues has successfully adapted this work to the cultural, ethical, and legal setting in Mexico as the early success in cord blood transplant from units in the La Raza bank demonstrates.

One of the intriguing questions raised by the Mexican success is whether the emergence of cord blood transplantation provides the key for developing countries seeking to start or grow unrelated transplant programs. Certainly, Novelo-Garza and colleagues have demonstrated that even with a small number of cord blood units, some patients will find a suitably matched graft. The number of transplants performed compared to the size of the registry is very encouraging. A further study of Mexico's population to fully understand the diversity represented would help determine whether this rate of selection can be sustained, and although it may be that the favorable selection rate will change over time as more is understood about the impact of HLA on cord blood selection, the relatively small size of the adult donor registry in Mexico suggests that for other countries seeking to establish unrelated transplant programs, the investment of resources to grow cord blood inventory may significantly enhance the development of those programs.

It should also be noted that the Mexican experience relies on a partnership between the Mexican health care system and government-supported scientific institutions to fund this effort. Clearly, the need for governmental investment into cord blood inventory growth is important, especially in countries with newly developing banks where a rapid buildup of inventory is desirable. Once a critical mass of banked units is achieved, it is expected that reimbursement for units ordered from inventory will allow a bank to replace and grow inventory at a self-sustaining rate, reducing or eliminating the need for governmental support in the future.





Unrelated Cord Blood Banks/Registries Annual Report 2012

14th Edition

Sponsored by:



World Marrow Donor Association

An annual publication of the World Marrow Donor Association in conjunction with the European Blood and Marrow Transplantation (EBMT) Group and NetCord Foundation

Share Information

www.worldmarrow.org



Table 6: Percentage of cord blood units provided for transplantation in relation to the number of cord blood units present (median shipping rate: 0.191%)

COUNTRY	Cord blood units PROVIDED	AVAILABLE	%
Japan ICBBN	1,175	30,063	3.908%
Mexico La Raza	35	748	3.342%
Mexico CNIS	39	1,555	2.508%
USA-NMDP Network***	1,870	185,484	1.008%
France	306	23,539	0.875%
Slovakia	12	1,724	0.696%
Mexico SACECU	2	304	0.658%
United Kingdom Anthony Nolan	9	1,520	0.592%
Germany Dueseldorf*	96	17,854	0.538%
Spain	288	55,509	0.519%
USA-New York*	294	58,151	0.506%
Singapore*	34	8,536	0.398%
Netherlands	12	3,237	0.371%
Sweden	9	2,545	0.354%
United Kingdom Bristol	55	17,804	0.312%
Australia	78	25,086	0.311%
China Guangzhou	14	4,544	0.308%
Italian Cord Blood Bank Network	88	29,114	0.299%
Switzerland	11	3,861	0.285%
Russia HPC	13	4,599	0.283%
Israel Sheba*	7	2,522	0.278%
Austria**	4	1,453	0.275%
Iran ICBB	4	1,625	0.246%
Finland	8	3,369	0.237%
Taiwan-Stemcyte*	24	10,992	0.218%
China Sichuan	7	3,429	0.204%
Brazil	16	7,562	0.204%
Belgium	33	16,360	0.199%
China Hong Kong	11	5,882	0.187%
China Beijing	26	14,405	0.180%
Turkey	1	587	0.170%
Germany	26	15,425	0.169%
Korea Catholic	4	2,409	0.166%
Korea NMDP	54	33,866	0.159%
Czech Republic	6	3,923	0.153%
Israel Hadassah	11	7,683	0.143%
Taiwan-Tzu CH	15	10,810	0.139%
Chile	1	751	0.133%
Cyprus	2	1,535	0.130%
Greece Hellenic	1	1,523	0.066%
Iran (NCBB)	1	1,534	0.065%
Russia Moscow	2	3,549	0.056%
Argentina	1	1,362	0.051%
Taiwan-Healthbanks*	3	6,254	0.048%
Canada Alma-Quebec	3	6,802	0.044%
Taiwan-Signet Babybanks	9	29,895	0.030%
USA-Calgene	0	3,859	0%
Vietnam	0	3,000	0%
Thailand	0	2,040	0%
Croatia	0	2,028	0%
Iran Royan	0	1,125	0%
Poland Poltransplant	0	871	0%
USA-Gift of Life*	0	894	0%
Greece Thessaloniki	0	462	0%
Slovenia	0	345	0%
Canada Victoria	0	216	0%
TOTAL	4,150	846,772	0.542%

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- * a part of these reported units are also reported under the NMDP Network
- ** for calculation the number of CBUs listed in BMDW (June 2013)
- *** total of all shipments of NMDP Cord Blood Banks (directly shipped and shipped via NMDP)



Cord blood banking and transplantation at the Mexican Institute of Social Security: the first 5 years

Angel Guerra-Marquez, Barbara Novelo-Garza, Araceli Malagón-Martínez, Alejandro Limon-Flores, Fernando Luna-Bautista, Luis Juan-Shum, Ines Montero-Ponce, Elizabeth Sanchez-Valle, Karina Peñaflor, Maria Antonieta Vélez-Ruelas, Yanin Romero-Juárez, and Hector Mayani

BACKGROUND: In January 2005, the Cord Blood Bank (CBB) at the Mexican Institute of Social Security initiated activities. Herein, we describe the experience generated during this period (January 1, 2005–December 31, 2009).

STUDY DESIGN AND METHODS: Good manufacturing practices and standard operating procedures were used to address donor selection, as well as umbilical cord blood (UCB) collection, processing, and cryopreservation. Based mainly on HLA and nucleated cell content, specific UCB units were thawed, processed, and released for transplantation.

RESULTS: A total of 589 UCB units were stored, representing 54% of the total number of units collected. Forty-eight units (8.14% of the stored units) were released for transplantation of 36 patients. Twenty-six patients (72% of cases) corresponded to patients with acute leukemia, five (14%) to patients with marrow failure, and the rest (five; 14%) to patients with hemoglobinopathies and other syndromes. The median number of nucleated cells infused per patient was $6.71 \times 10^7/\text{kg}$ and the median number of CD34+ cells was $4.8 \times 10^5/\text{kg}$. Current engraftment data indicate that engraftment occurred in 56%, and no engraftment in 44%, of cases. Engraftment was more frequent (59%) in patients that received more than 3×10^7 total nucleated cells (TNCs)/kg body weight, than in those receiving fewer than 3×10^7 TNCs/kg (40%). Myeloid engraftment was observed 7 to 54 days posttransplant (median, 23 days), whereas platelet engraftment was detected on Days 12 to 87 posttransplant (median, 38 days). To date, the disease-free survival rate was 41% and the overall survival was 47%, with survival periods of 126 to 1654 days.

CONCLUSION: Although the experience presented herein is still limited and the period of analysis is still short, the results obtained during these 5 years are encouraging.

During the past 20 years, umbilical cord blood (UCB) transplantation has become a first-line therapy for specific hematologic conditions, particularly in pediatric patients. Interestingly, its application has expanded to adult patients through the use of large single- or double-unit transplants.¹ Also during the past decade, single institutions, as well as multinational organizations and government regulatory agencies, have been actively involved in establishing regulatory issues regarding UCB collection, processing, and banking.^{2,3} It is estimated that more than 20,000 UCB transplants have been performed worldwide and that more than 400,000 UCB units are currently stored

ABBREVIATIONS: CBB = Cord Blood Bank; CFC(s) = colony-forming cell(s); IMSS = Mexican Institute of Social Security; UCB = umbilical cord blood.

From the Umbilical Cord Blood Bank and the Department of Pediatric Hematology, La Raza Medical Center; the Department of Hematology, Pediatrics Hospital and the Department of Hematology, Medical Specialties Hospital, Siglo XXI Medical Center; the Department of Pediatrics, Carlos MacGregor Hospital; the Oncology Research Unit, Oncology Hospital, Siglo XXI Medical Center, Mexican Institute of Social Security, Mexico City, Mexico; and the Department of Hematology, Medical Specialties Hospital, Mexican Institute of Social Security, Puebla City, Mexico.

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TRANSFUSION **.*.***.**.



¿Porqué Acreditarse?

La acreditación es un facilitador de la calidad y un componente esencial de la buena gestión clínica.

Ofrecer células troncales seguras, confiables y efectivas, a través de:

- Control del proceso por medio de métodos estandarizados.
- Rastreabilidad de los donantes de las células para seguridad del receptor.
- Cumplir con los estándares internacionales para selección, obtención, análisis, conservación, preparación, validación, suministro, utilización, destino final y distribución.
- Contar con la preservación óptima durante el transporte hacia los centros de trasplante.
- La validación de los procesos para contar con resultados confiables y brindar mayor seguridad al paciente

¿Porqué Acreditarse?

Brindar “Calidad Total y Confianza” en todos los procesos de un banco de células troncales hematopoyéticas



Evitar ser un “charlatán” en un país donde no existe instrumentos regulatorios. Donde los pacientes buscan obtener terapias con células troncales, presentando graves riesgos para la salud, poniendo en riesgo la integridad de la investigación con células madre del país.

(Revista Redbioética/UNESCO, Año 3. 2(6). 63-78, Julio – Diciembre 2012-ISSN 2077-9445 Medina Arellano Ma. De Jesús- The Rise of Stem Cell Therapies in Mexico)

MUCHAS GRACIAS

