

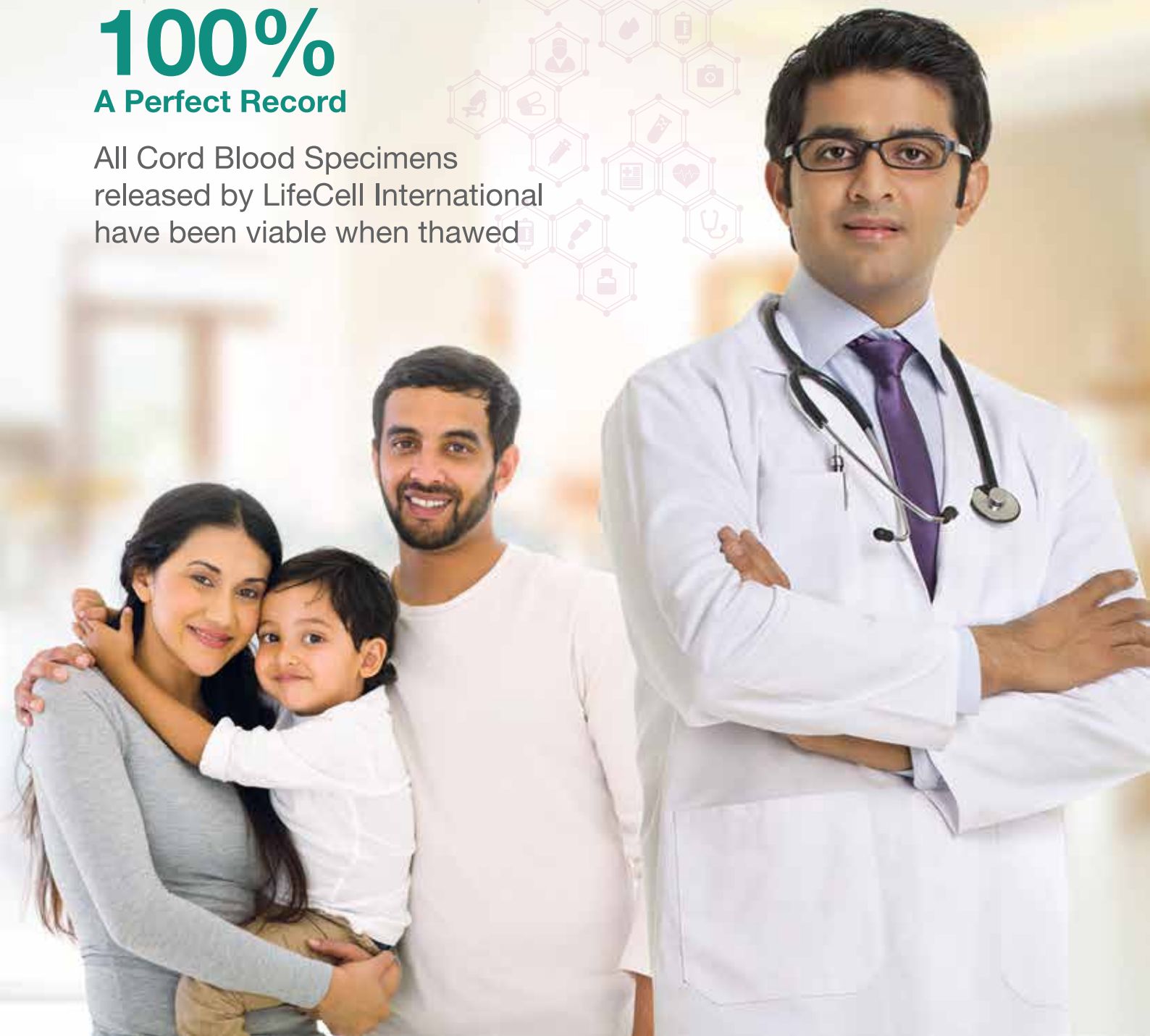
STEM CELL TRANSPLANTATION & INFUSION RECORD

A History Of Success

100%

A Perfect Record

All Cord Blood Specimens
released by LifeCell International
have been viable when thawed





Private Bank / Public Bank



LifeCell - "Community Bank"

LifeCell's Community Banking - The Best Solution to Meet the Recommendations, Challenges & Need of the Hour

Abides by the Recommendations of IAP & IMA

LifeCell's Community Stem Cell Bank works similar to a Public Bank. Parents contribute their baby's cord blood stem cells to a common pool for use by themselves and other members of the community. This increases the chances of finding a suitable matching donor and thereby expands the treatment options for patients. Thus, the Community Banking model aligns with the recommendations of both the Indian Academy Of Pediatrics (IAP) and Indian Medical Association (IMA). Not only does Community Banking solve the challenges of low inventory and high costs of the public banking model, it is also a more sustainable business model compared to public banks.



Dr. Sandip Shah, MBBS, MD (Medicine),
Senior Medical Oncologist, Hematologist & Bone Marrow Transplant Physician,
Ahmedabad, Gujarat



Dr. Rahul Bhargava, MBBS, MD (Medicine), DM (Clinical Haematology)
Hematologist, Haemato-Oncologist & Bone Marrow Transplant
Physician, Gurugram, Haryana



Dr. Purvish Parikh, MBBS, MD, DNB, FICP, PhD, ECMO, CPI, MBA,
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Dr. Mahesh Rajashekaraiah, MBBS, MD (Internal Medicine),
DM (Clinical Hematology), Hematologist, Haemato-Oncologist &
Bone Marrow Transplant Physician, Bengaluru, Karnataka



Dr. Shraddha Chandak, MBBS, DCH, DNB, FIAP
Consultant Pediatric Haemato-Oncologist &
Immunologist, Aurangabad, Maharashtra



“

Doctor's Voice

Being in this field for almost 17 years people do turn up to me for suggestions regarding the option of saying "yes" or "no" to cord blood banking. I am definitely in a better position to say YES to them after I heard about your Community based cord blood banking program. It is unfortunate that our country lacks the awareness about cord blood banking and the ones who know a little about it are sceptical to go for it. Nevertheless, our country is in the "willing to learn" category and I am sure in the next few years most of the pregnant mothers will be opting for cord blood banking, hopefully all of them with LifeCell.

- Dr. Praveen Clement, Transplant Coordinator, Marrow Donor Registry India (MDRI)

Likelihood of using own cord blood is very small (less than 0.04%). Hence, the donation of cord blood to public bank is recommended because there is 100 times more likely chance of release of a unit from public bank compared to a private bank. - Recommendations by ACOG, AAP and ASBMT.

In majority of blood disorders, the child's own stored cord blood cannot be used for the same child as they will carry the same genetic defect. - Padma Shri Dr. K. K. Aggrawal, Immediate Past President of Indian Medical Association (IMA)- April, 2018.

According to the current literature, Community Banking is better than Private Banking. - Dr. Ashima Taneja, MD (Obst & Gynec), Dayanand Medical College and Hospital, Ludhiana, Punjab.

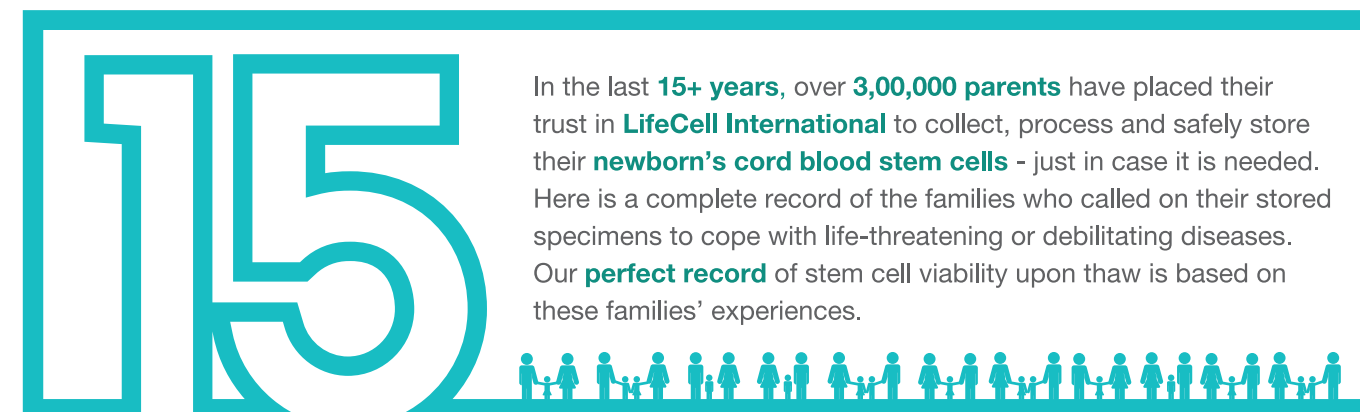
Community stem cell banking is really a need of this era and please make sure to take this idea especially to remote areas. - Dr. Yogita Chandarvanshi, Senior Consultant and Medical Director of Chandrayan Health Care, Raipur, Chhattisgarh.

Dr. Niranjan N Rathod, Associate Director & Head of Department, Haemato-Oncology & Bone Marrow Transplant, Nanavati Super Speciality Hospital, Mumbai said, "We have a huge number of patients suffering from fatal blood disorders like Blood Cancer and Thalassemia Major for whom the last resort is a Blood Stem Cell transplant. For patients who could not find a match within their family there was no hope. It is only with help of unrelated donor registries that there is a ray of hope for such patients."

Private banks continue storing umbilical cords, with no one questioning its futility. This kind of singular banking systems is reaping little gain but with the general lack of awareness, parents are falling into deep traps. The reserves should be turned into pools of sharing resource. Patients can be treated by choosing the closest match from the available pool. - Dr A. Kannan, Head of Paediatrics, Meenakshi Mission Hospital, Madurai, Tamil Nadu.

Routine non-directed cord blood and cord banking as a form of 'biological insurance' against future disease should be discouraged. Restructuring the way umbilical cord blood is stored and shared will present new paradigms of treatment. Filling the large gap between what's available and what's usable is now the need of the hour. - Dr. Prathima Reddy, Senior Obstetrician and Gynaecologist, Director of Fortis La Femme Hospital, Bangalore, Karnataka.

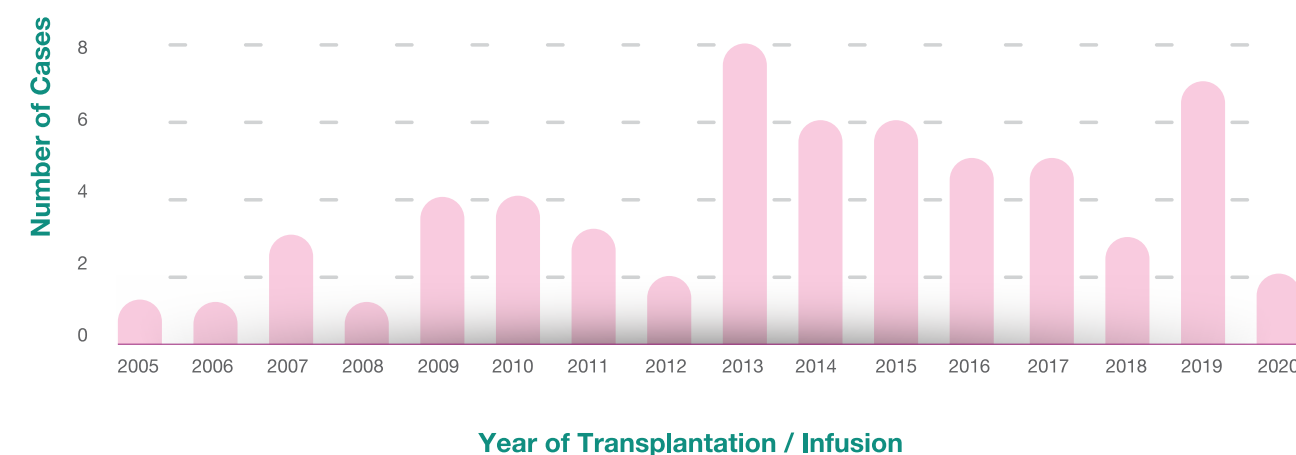
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Total number of cord blood units retrieved =

61

Number of Cases vs. Year of Transplantation / Infusion

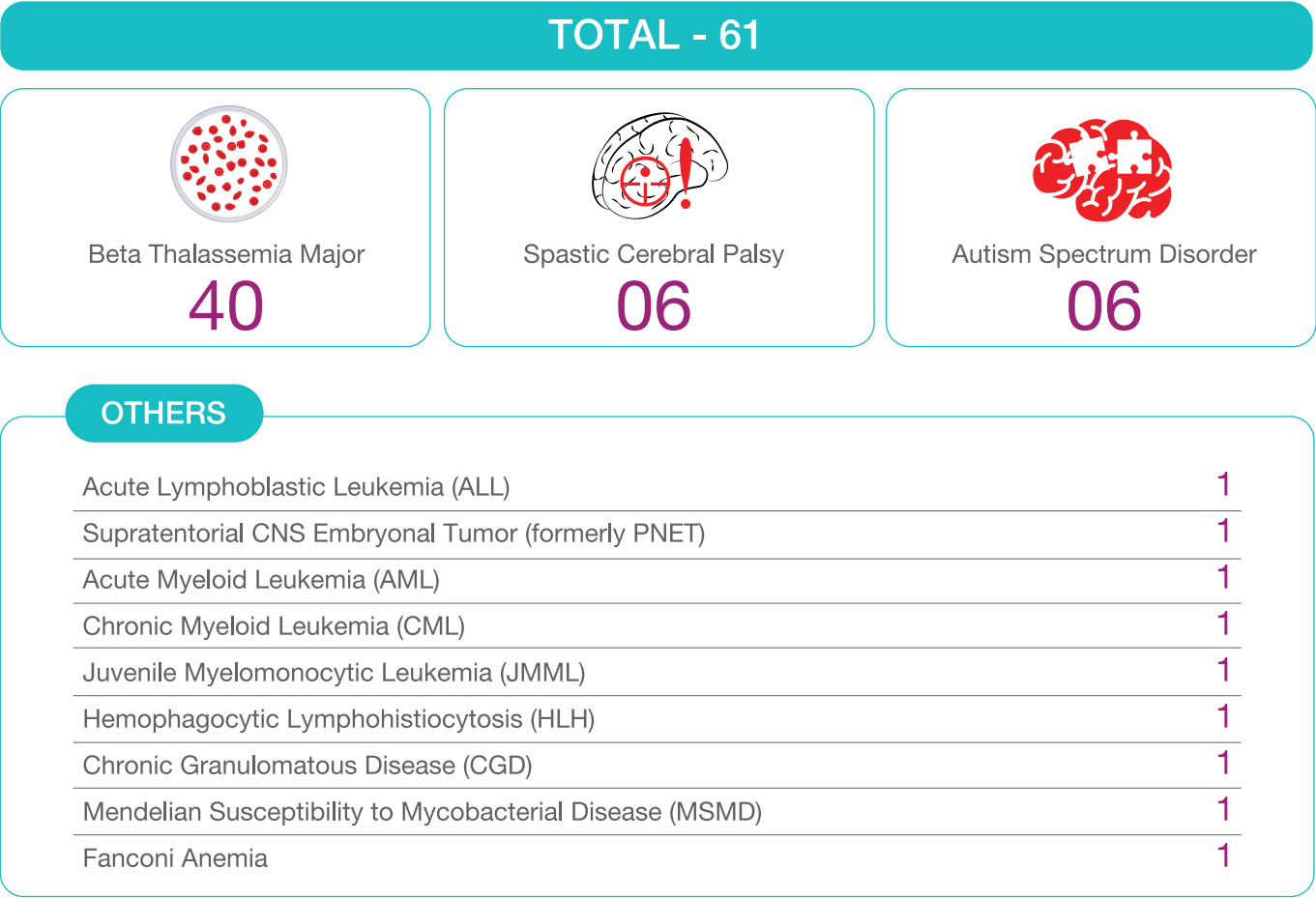


Summary Of Our Retrieval Experience







Medical Conditions Treated Using The Stored Cord Blood Units

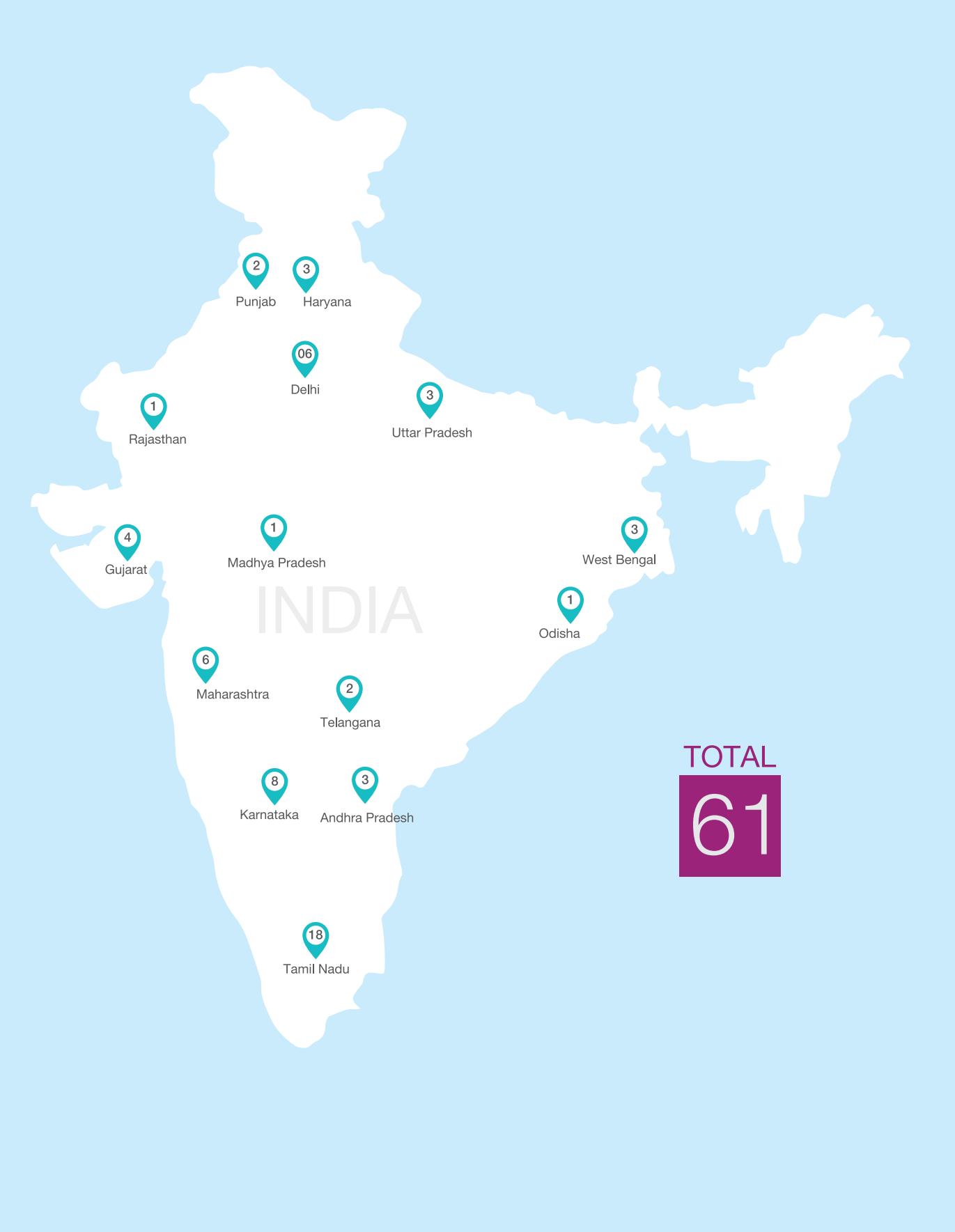
*In many cases, to increase the stem cell dosage, patients received both cord blood and bone marrow stem cells from the same sibling donor.



Medical Conditions (Diagnosis) And Country of Stem Cell Transplantation / Infusion

| Medical Conditions / Diagnosis | India | USA | Singapore | Thailand | TOTAL |
|--|---|---|---|---|-------|
| |  |  |  |  | |
| Beta Thalassemia Major | 38 | 0 | 1 | 1 | 40 |
| Spastic Cerebral Palsy | 1 | 5 | 0 | 0 | 6 |
| Autism Spectrum Disorder | 0 | 5 | 1 | 0 | 6 |
| Acute Lymphoblastic Leukemia (ALL) | 0 | 1 | 0 | 0 | 1 |
| Supratentorial CNS Embryonal Tumor (formerly PNET) | 1 | 0 | 0 | 0 | 1 |
| Acute Myeloid Leukemia (AML) | 1 | 0 | 0 | 0 | 1 |
| Chronic Myeloid Leukemia (CML) | 1 | 0 | 0 | 0 | 1 |
| Juvenile Myelomonocytic Leukemia (JMML) | 1 | 0 | 0 | 0 | 1 |
| Hemophagocytic Lymphohistiocytosis (HLH) | 1 | 0 | 0 | 0 | 1 |
| Chronic Granulomatous Disease (CGD) | 1 | 0 | 0 | 0 | 1 |
| Mendelian Susceptibility to Mycobacterial Disease (MSMD) | 1 | 0 | 0 | 0 | 1 |
| Fanconi Anemia | 1 | 0 | 0 | 0 | 1 |
| TOTAL | 47 | 11 | 2 | 1 | 61 |

Where Do These Indian Families Belong To?



Hospitals Where These Stem Cell Transplantations / Infusions Were Performed

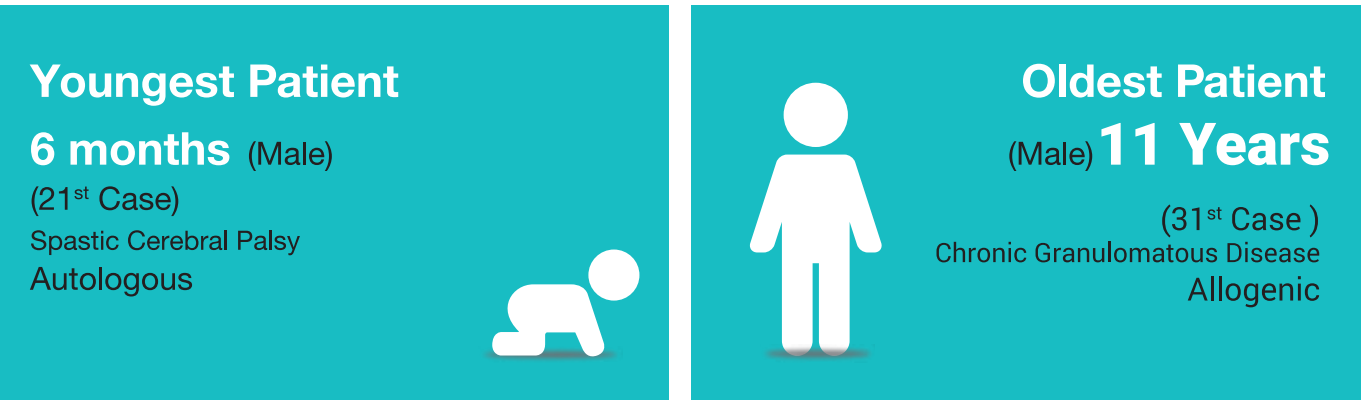
| Name Of Hospital | Number Of Cases |
|---|-----------------|
| INDIA | |
| • Apollo Speciality Hospital, Chennai, Tamil Nadu, India | 25 |
| • Dr. B. L. Kapur Memorial Hospital, New Delhi, India | 6 |
| • Narayana Hrudayalaya Health City, Bengaluru, Karnataka, India | 4 |
| • Christian Medical College (CMC), Ludhiana, Punjab, India | 2 |
| • Fortis Malar Hospital, Chennai, Tamil Nadu, India | 1 |
| • Sir Ganga Ram Hospital, Rajinder Nagar, New Delhi, India | 1 |
| • Sterling Hospital, Ahmedabad, Gujarat, India | 1 |
| • Rajiv Gandhi Cancer Institute and Research Center, Delhi, India | 2 |
| • Medanta - The Medicity Hospital, Gurugram, Haryana, India | 2 |
| • Indraprastha Apollo Hospital, New Delhi, India | 1 |
| • NH SRCC Children's Hospital, Mumbai, Maharashtra, India | 2 |
| USA | |
| • Duke University Medical Center, Durham, North Carolina, USA | 9 |
| • Carolinas Cord Blood Bank At Duke University, Durham, North Carolina, USA | 2 |
| SINGAPORE | |
| • Mount Elizabeth Hospital, Singapore | 1 |
| • KK Women's and Children's Hospital, Singapore | 1 |
| THAILAND | |
| • Siriraj Hospital, Bangkok, Thailand | 1 |

Physicians Who Performed These Stem Cell Transplantations / Infusions

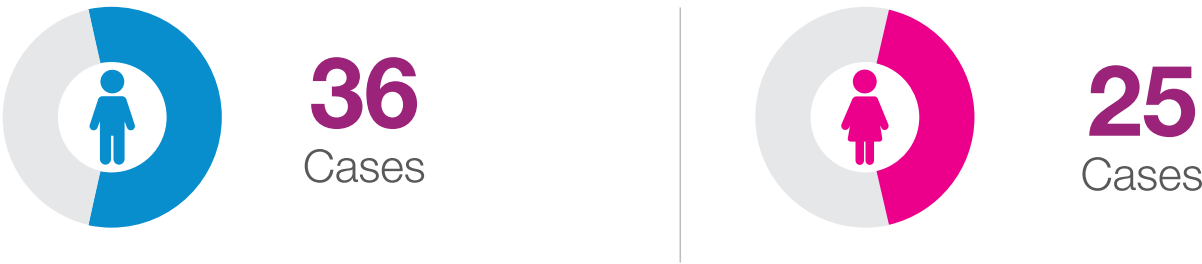
| Name Of Doctor / Physician | Number Of Cases |
|---|-----------------|
| INDIA | |
| • Dr. Revathi Raj, Apollo Speciality Hospital, Chennai, Tamil Nadu, India | 24 |
| • Dr. Dharma Choudhary, Dr. B. L. Kapur Memorial Hospital, New Delhi, India | 5 |
| • Dr. Sunil Bhat, Narayana Hrudayalaya Health City, Bengaluru, Karnataka, India | 3 |
| • Dr. M. Joseph John, Christian Medical College (CMC), Ludhiana, Punjab, India | 2 |
| • Dr. Ruchira Misra, NH SRCC Children's Hospital, Mumbai, Maharashtra, India | 2 |
| • Dr. Satya P. Yadav, Medanta - The Medicity Hospital, Gurugram, Haryana, India | 2 |
| • Dr. Satya P. Yadav, Sir Ganga Ram Hospital, Rajinder Nagar, New Delhi, India | 1 |
| • Dr. Gaurav Kharya, Dr. B. L. Kapur Memorial Hospital, New Delhi, India | 1 |
| • Dr. Gaurav Kharya, Indraprastha Apollo Hospital, New Delhi, India | 1 |
| • Dr. Dinesh Bhurani, Rajiv Gandhi Cancer Institute and Research Center, Delhi, India | 1 |
| • Dr. Dinesh Bhurani, Sterling Hospital, Ahmedabad, Gujarat, India | 1 |
| • Dr. Ranjan Kumar Mohapatra, Apollo Speciality Hospital, Chennai, Tamil Nadu, India | 1 |
| • Dr. V. Murugan, Fortis Malar Hospital, Chennai, Tamil Nadu, India | 1 |
| • Dr. Narendra Agrawal, Rajiv Gandhi Cancer Institute and Research Center, Delhi, India | 1 |
| • Dr. Sarath Damodar, Narayana Hrudayalaya Health City, Bengaluru, Karnataka, India | 1 |
| USA | |
| • Dr. Jessica M. Sun, Duke University Medical Center, Durham, North Carolina, USA | 7 |
| • Dr. Joanne Kurtzberg, Carolinas Cord Blood Bank At Duke University, Durham, North Carolina, USA | 4 |
| SINGAPORE | |
| • Dr. Patrick Tan, Mount Elizabeth Hospital, Singapore | 1 |
| • Dr. Joyce Lam Ching Mei, KK Women's and Children's Hospital, Singapore | 1 |
| THAILAND | |
| • Dr. Vinai Suwatte, Siriraj Hospital, Bangkok, Thailand | 1 |

Total number of cord blood units retrieved = 61
(*as on Feb 2020)

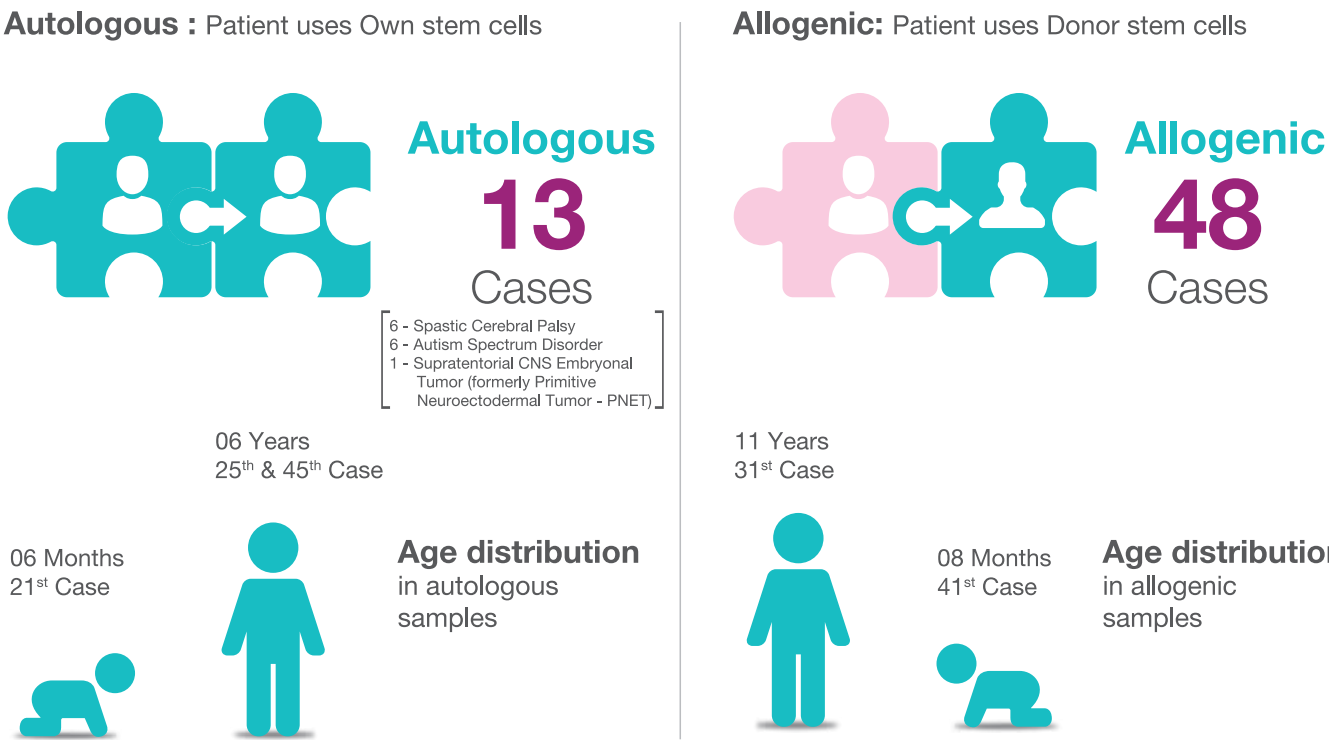
Age Range of patients who received the stem cell transplantation / infusion



Gender Distribution

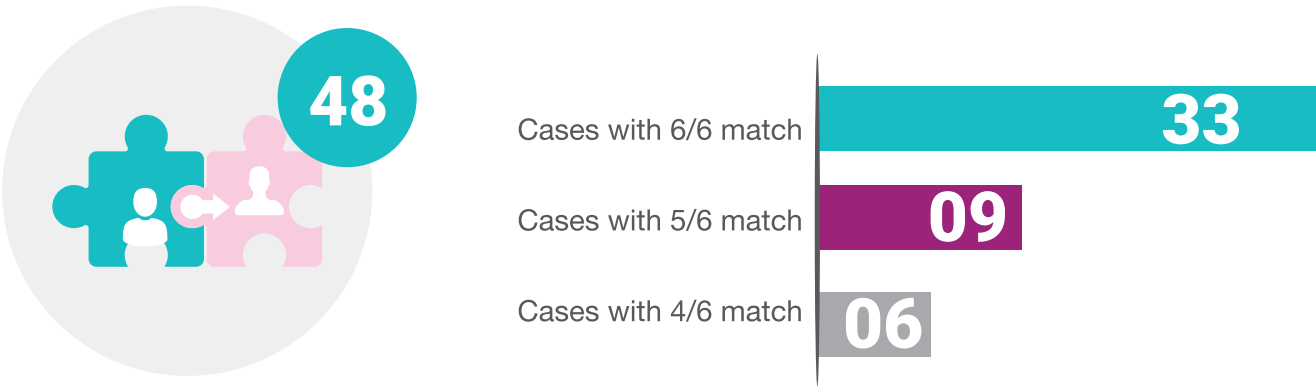


Type Of Transplantation / Infusion



Distribution of HLA Matching Between Siblings

Human Leukocyte Antigens are proteins on the surface of our cells that helps the immune system to identify the cells that belong to our body. The best transplant outcome happens when a patient's HLA and the donor's HLA closely match.



ALLOGENIC CASES

HLA typing is used to match the compatibility of the patient with a donor for stem cell transplant. A 4 out of 6 HLA match (~67% match) between the patient and the donor is sufficient for umbilical cord blood stem cell transplantation while other stem cell sources may require 100% full match.

Reference: http://www.nationalcordbloodprogram.org/public_hla_search.html

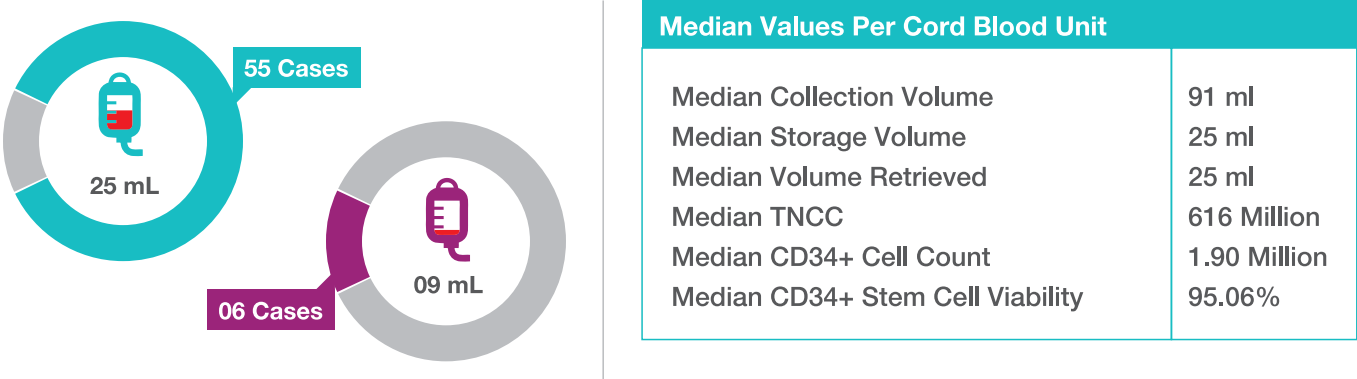
Type Of Storage

For disaster management, back-up and added retention security, LifeCell offers an industry-exclusive service called Dual Site Facility to safeguard the cord blood units at its licensed laboratories situated at Chennai and Gurugram.

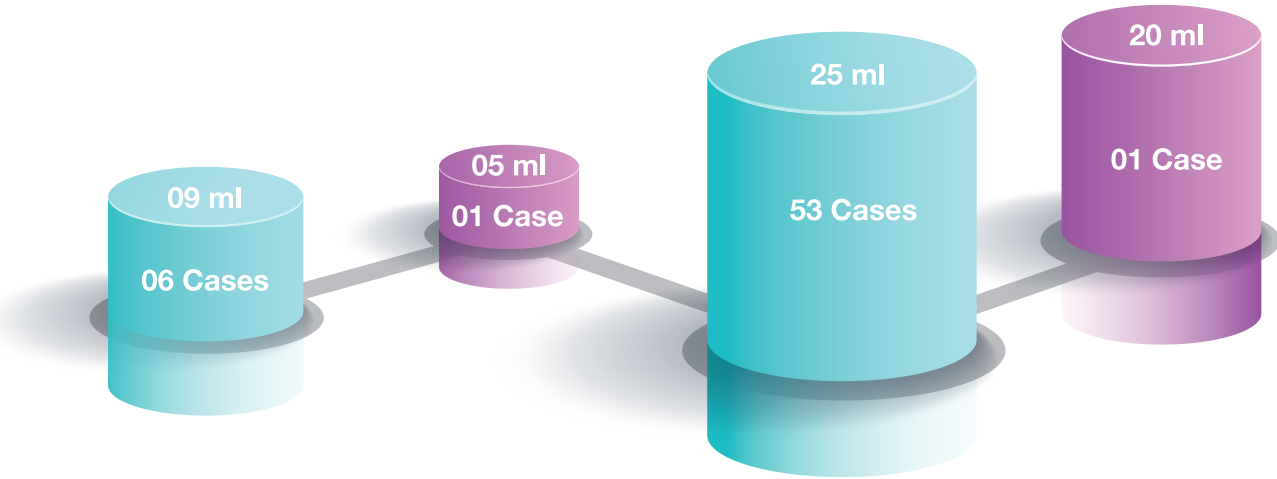


This is a testimony that cord blood units stored at two storage locations are accepted for transplantation / infusion by leading hospitals in India (17 cases) and abroad (USA - 3 cases & Singapore - 1 case).

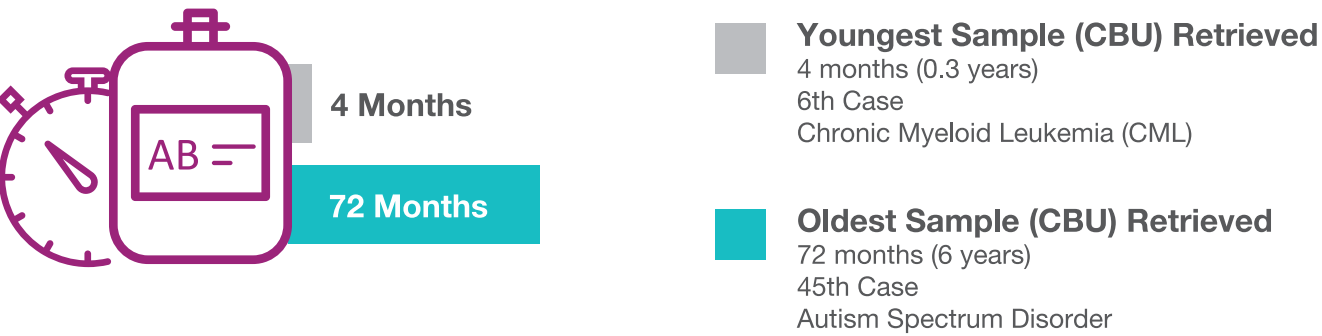
Volume Distribution Of CBU At The Time Of Storage



Volume Distribution Of CBU At The Time Of Retrieval



How Long Were The Cord Blood Units Stored Before Retrieval



DID YOU KNOW?

“Cord blood donated 20 years ago at the BMDI Public Cord Blood Bank, Melbourne, Australia, has been shipped to the other side of the world at Cell Therapy Laboratory, USA where it is being prepared for infusion in a young girl who is waiting in a hospital to receive new blood stem cells that will hopefully treat her leukemia. Even after 20 years, 99.4% of the cryopreserved cells were recovered, with a stem cell viability of 87%, according to the Director of the bank from which the unit was shipped.” (Ref : <https://bit.ly/2TdOT8g>)

LifeCell Case Studies

Section I: Thalassemia Major

CASE STUDY # 1:

Printed from
THE TIMES OF INDIA

His sister's keeper: Brother's blood is boon of life

TNN | Sep 17, 2009, 02:52 AM IST



His sister's keeper: Brother's blood is boon of life

CHENNAI: Senthil Kumar and Sarojini were shattered when their 18-month-old daughter, Thamirabharani, was diagnosed with thalassaemia. The blood disorder left the infant, born in 2000, at the mercy of transfusions and with little energy for anything else. [\(Watch Video\)](#) Sarojini aborted her next two pregnancies, fearing a repeat of the disorder in her children and it began to look like Thamirabharani would have neither a good life nor a sibling. Today, she has both – and, to double the family's joy, her brother also turned out to be her saviour.

Giving a happy ending to a poignant family tale and raising fresh hope of leveraging stem cell therapy, a group of doctors and specialists in Chennai and Coimbatore have registered the first successful treatment of thalassaemia in a child using a sibling's umbilical cord blood. Stem cells

extracted from the cord blood during Pugazhendi's birth were transplanted in Thamirabharani in March. After the mandatory five months' observation period, doctors on Wednesday announced Thamirabharani cured of thalassaemia.



Dr. Revathi Raj, Pediatric Hematologist at Apollo Speciality Hospital, Chennai, Tamil Nadu, India performed this blood stem cell transplantation in 2009 using Thamirabharani's younger brother's bone marrow and cord blood stem cells together.

LifeCell assisted this family with INR 12 lakh to offset the transplant related expenses on humanitarian grounds.

Transplant Outcomes For Thalassemia Major Cases Facilitated By LifeCell

(*Data as on February 2020)

The youngest patient was 2 years and the oldest 10 years in age. There were total 20 males and 20 females. A standard chemotherapy conditioning regimen was used in all the patients to prepare them for the hematopoietic stem cell transplantation. On follow up of first 21 cases, ~95% of the patients had one year disease-free survival. In our experience so far, 10% of cases were with 4/6 match, 22.5% cases with 5/6 match and 67.5% cases with 6/6 full match. To increase the stem cell dosage, patients received both cord blood and bone marrow stem cells from the same sibling donor.



CASE STUDY # 2: Nitya's Story

- Nitya Dua, is like any other teenager, but not so long ago! Her parents were quite concerned and worried when she repeatedly fell sick. They were shocked to learn that Nitya was diagnosed with Thalassemia Major and needed two units of blood transfusion every month.
- Her father, Mohit, a businessman from Ghaziabad, read about bone-marrow transplants being used to treat Thalassemia, and when his son was born in 2009, he had the infant's cord blood banked with LifeCell International.
- In Sep 2012, Dr. Dharma Choudhary at Dr. B. L. Kapur Memorial Hospital, New Delhi, India, performed a bone marrow transplantation on Nitya using cord blood and bone marrow of Nitya's brother.
- Nitya showed progressive recovery from day one and showed good engraftment of the new stem cells into his bloodstream. She was declared disease-free and was discharged from the hospital subsequently. She is now cured and is focusing on her studies.
- Would Mr. Mohit Dua recommend expectant parents to get their baby's cord blood banked: "How can I not? It did help," he says.
- Nitya is an example that such incurable diseases can be treated with the best quality stem cells.

LifeCell **Annual Transplant Follow-up Form**

Date: 16/9/14 (mm/dd/yyyy)

Patient Name: [Redacted] Age (yrs): 10.10

LifeCell CRM ID: [Redacted] Transplant Physician: Dr. DHARMA CHAUDHARY

Transplant Center (Hospital Address): BL KAPUR MEMORIAL HOSPITAL, NEW DELHI-110005

Transplant Date/Time: 01/07/2011 Transplant done for (Disease): THALASSEMIA MAJOR

1. Quality of life of the patient: ☒ Good ☐ Better ☐ Improved ☐ Not Improved

2. Post Transplant Hospitalization In the past: ☐ Yes ☒ No

Comments (if yes): _____

3. Concomitant medication: ☐ On ☒ Stopped

Comments (if medication is on): _____

4. Laboratory testing in the past: ☒ Done ☐ Not done

(Abnormal values if any): None

(NOTE: Kindly attach the copy of laboratory reports in case of abnormal values)

5. Whether intended dysfunction is: ☒ Cured ☐ Improving ☐ Not Improving

6. GVHD: ☐ Yes ☒ No (If yes, please provide details): _____

7. Chimerism: ☐ Yes ☒ No (If yes, please provide details): Complete donor chimerism

Comments (if yes): _____

Additional comment on Patient's examination (if any): None

Form completed by (Printed name): MAHANT DHANISH Date: 16/9/14

Signature: [Signature] Telephone: 1226

Reviewed by: [Signature] Date: 16/9/14

Please send the filled-up form to:
LifeCell International, # 28, Vardhola Kalamandalam Main Road, Kesthikottaiyur, Chennai-600127, Phone: +91-44-7445353, Or
Fax the form to +91-44-7445354

LC/CRYGEN/SOP-002/FOM-20 Effective: 07/08/2014 Page 1 of 1

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e info@blkhospital.com www.blkhospital.com

Section II : Autism Spectrum Disorder (ASD)

Stem Cells Transl Med. 2017 May;6(5):1332-1339. doi: 10.1002/sctm.16-0474. Epub 2017 Apr 5.

Autologous Cord Blood Infusions Are Safe and Feasible in Young Children with Autism Spectrum Disorder: Results of a Single-Center Phase I Open-Label Trial.

Dawson G¹, Sun JM², Davlanis KS¹, Murias M^{1,3}, Franz L¹, Troy J², Simmons R², Sabatos-DeVito M¹, Durham R², Kurtzberg J².

Author information

- 1 Duke Center for Autism and Brain Development, Duke University Medical Center.
- 2 Robertson Clinical and Translational Cell Therapy Program, Duke University Medical Center.
- 3 Duke Institute for Brain Sciences, Duke University Medical Center, Durham, North Carolina, USA.

Abstract

Despite advances in early diagnosis and behavioral therapies, more effective treatments for children with autism spectrum disorder (ASD) are needed. We hypothesized that umbilical cord blood-derived cell therapies may have potential in alleviating ASD symptoms by modulating inflammatory processes in the brain. Accordingly, we conducted a phase I, open-label trial to assess the safety and feasibility of a single intravenous infusion of autologous umbilical cord blood, as well as sensitivity to change in several ASD assessment tools, to determine suitable endpoints for future trials. Twenty-five children, median age 4.6 years (range 2.26-5.97), with a confirmed diagnosis of ASD and a qualified banked autologous umbilical cord blood unit, were enrolled. Children were evaluated with a battery of behavioral and functional tests immediately prior to cord blood infusion (baseline) and 6 and 12 months later. Assessment of adverse events across the 12-month period indicated that the treatment was safe and well tolerated. Significant improvements in children's behavior were observed on parent-report measures of social communication skills and autism symptoms, clinician ratings of overall autism symptom severity and degree of improvement, standardized measures of expressive vocabulary, and objective eye-tracking measures of children's attention to social stimuli, indicating that these measures may be useful endpoints in future studies. Behavioral improvements were observed during the first 6 months after infusion and were greater in children with higher baseline nonverbal intelligence quotients. These data will serve as the basis for future studies to determine the efficacy of umbilical cord blood infusions in children with ASD. *Stem Cells Translational Medicine* 2017;6:1332-1339.

© 2017 The Authors. *Stem Cells Translational Medicine* published by Wiley Periodicals, Inc. on behalf of AlphaMed Press.

KEYWORDS: Autism spectrum disorder; Autologous umbilical cord blood; Cell therapy

PMID: 28378499 PMCID: PMC5442708 DOI: 10.1002/sctm.16-0474

Significance Statement

This phase I study demonstrates that it is safe and feasible to perform autologous umbilical cord blood infusions in young children with autism spectrum disorder and identifies several promising outcome measures for use in future trials.

5 out of total 25 children who participated in this US FDA-approved clinical trial had their own cord blood stem cells banked at birth with LifeCell which turned out to be beneficial. The children underwent the infusion of their own cord blood stem cells under the able supervision of world renowned physicians Dr. Joanne Kurtzberg and Dr. Jessica Sun at Duke University Medical Center, Durham, North Carolina, USA.

In July 2019, one of LifeCell Client's Child got her Own Cord Blood Infused to treat ASD in a SingHealth Centralised Institutional Review Board (CIRB) Approved Clinical Trial led by Dr. Joyce Lam Ching Mei, Paediatric Haematology / Oncology, Pathology Laboratory Medicine at KK Women's & Children's Hospital, Singapore.



Case example: Baseline assessment

- No words; limited vocalizations
- Little use of gestures
- Little emotional engagement



Case example: 12 month assessment

- Increase in number of word
- Spontaneous use of full sentences and gestures
- Use of imaginary play
- Increased emotional response and sustained eye contact
- Language score increased from 62 to 97 (100 is average)
- IQ increased from 54 to 82

Encouraging Preliminary Data:

The researchers found that while at **Baseline Assessment**, kid had limited vocalizations, little use of gestures and little emotional engagement. At **12-Month Assessment**, the kid showed improvement in increase in number of spoken words, spontaneous use of full sentences and gestures, use of imaginary play, increased emotional response and sustained eye contact. The language score increased from 62 to 97 (100 is average), while the IQ increased from 54 to 82.

This trial identified outcome measures that are feasible, sensitive to change, and developmentally-appropriate, and thus are suitable for use in future clinical trials to test the efficacy of cord blood therapy for the treatment of young children with ASD.



Watch This Video From 15.45 mins To 17.16 mins

LifeCell Client Testimonial:

Interview Of Mr. Apurba Dey Singha, Father of Master Apartim Who Underwent Autologous Cord Blood Infusion At Duke University, USA

Apratim gets cord blood therapy for autism

April 2018



Apratim Dey Singha of Kolkata, India, is now four years old. Although his birth was a month premature, as an infant he passed all his developmental milestones on time. It was not until he reached 18 months of age that his parents noticed his communication skills were not progressing like other children.

"We were worried but our local paediatrician was positive. He asked us to observe him for another six months. We saw no changes in his behaviour."
- Apurba Dey Singha, Apratim's father

Apratim saw a specialist in Delhi who diagnosed him as having Autism Spectrum Disorder (ASD). Autism refers to a range of conditions characterized by challenges with social skills, repetitive behaviors, speech and nonverbal communication, as well as by unique strengths and differences. Each person with autism presents differently, but has enough of the traits to be recognized as being on the spectrum.



Apratim's family researched interventions to improve his language skills and tried several approaches. They learned that in 2014, the same year Apratim was born, Duke University launched the first in a series of clinical trials [treating autism with cord blood stem cells](#).

Results from the first Duke trial of cord blood therapy for autism were [published open access](#) in April 2017. In that pilot study, participants showed significant improvements in measures of social skills, expressive vocabulary, severity of autism behavior patterns, and eye-tracking response to stimuli. The children's scores were measured by both parents and clinicians using established behavioral scales developed for autism. The observed improvements appeared within 6 months of cord blood therapy.

In a [press release](#) from Duke University, lead investigator Dr Joanne Kurtzberg expressed "cautious optimism" but urged parents not to jump to conclusions:

"Parents of children with autism should not interpret these results as conclusively showing effectiveness of this treatment. There is much work still to be done in much larger, randomized clinical studies before we can draw any firm conclusions about effectiveness." - Joanne Kurtzberg, MD

Apratim's cord blood had been stored since birth with LifeCell International, the largest family cord blood bank in India. His parents asked to participate in a clinical trial at Duke, and after a number of tests he was accepted. The therapy took place in the United States in July 2017.

In the 9 months since the cord blood therapy, his father says he has seen significant changes in Apratim. He is communicating more, his cognitive skills have improved, he's started school, and he likes playing with his friends.

"We were happy that we made a wise decision of preserving our baby's umbilical cord stem cells at birth in 2014 with LifeCell, which were used to treat my son for autism. Today, we are seeing great progress in terms of development milestones in my son." - Apurba Dey Singha

Section III : Cerebral Palsy



STEM CELLS
TRANSLATIONAL MEDICINE

CORD BLOOD

Authored by a member of
 CORD BLOOD
ASSOCIATION

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<http://dx.doi.org/10.1002/sctm.17-0102>

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Effect of Autologous Cord Blood Infusion on Motor Function and Brain Connectivity in Young Children with Cerebral Palsy: A Randomized, Placebo-Controlled Trial

JESSICA M. SUN ^a, ALLEN W. SONG, ^b LAURA E. CASE, ^c MOHAMAD A. MIKATI, ^d KATHRYN E. GUSTAFSON, ^e RYAN SIMMONS, ^a RICKI GOLDSTEIN, ^f JODI PETRY, ^c COLLEEN McLAUGHLIN, ^a BARBARA WATERS-PICK, ^g LYON W. CHEN, ^b STEPHEN WEASE, ^h BETH BLACKWELL, ^h GORDON WORLEY, ^d JESSE TROY, ^a JOANNE KURTZBERG ^a

Key Words. Autologous stem cell transplantation • Cellular therapy • Clinical Trials • Cord blood • Human cord blood • Nervous system • Umbilical cord blood

ABSTRACT

Cerebral palsy (CP) is a condition affecting young children that causes lifelong disabilities. Umbilical cord blood cells improve motor function in experimental systems via paracrine signaling. After demonstrating safety, we conducted a phase II trial of autologous cord blood (ACB) infusion in children with CP to test whether ACB could improve function (ClinicalTrials.gov, NCT01147653; IND 14360). In this double-blind, placebo-controlled, crossover study of a single intravenous infusion of $1-5 \times 10^7$ total nucleated cells per kilogram of ACB, children ages 1 to 6 years with CP were randomly assigned to receive ACB or placebo at baseline, followed by the alternate infusion 1 year later. Motor function and magnetic resonance imaging brain connectivity studies were performed at baseline, 1, and 2 years post-treatment. The primary endpoint was change in motor function 1 year after baseline infusion. Additional analyses were performed at 2 years. Sixty-three children (median age 2.1 years) were randomized to treatment ($n = 32$) or placebo ($n = 31$) at baseline. Although there was no difference in mean change in Gross Motor Function Measure-66 (GMFM-66) scores at 1 year between placebo and treated groups, a dosing effect was identified. In an analysis 1 year post-ACB treatment, those who received doses $\geq 2 \times 10^7/\text{kg}$ demonstrated significantly greater increases in GMFM-66 scores above those predicted by age and severity, as well as in Peabody Developmental Motor Scales-2 Gross Motor Quotient scores and normalized brain connectivity. Results of this study suggest that appropriately dosed ACB infusion improves brain connectivity and gross motor function in young children with CP. STEM CELLS TRANSLATIONAL MEDICINE 2017;6:2071-2078

SIGNIFICANCE STATEMENT

Results of this trial suggest that, when adequately dosed, an intravenous infusion of autologous umbilical cord blood improves whole brain connectivity and motor function in young children with cerebral palsy.

5 out of 63 children who participated in this US FDA-approved clinical trial had their cord blood preserved at birth with LifeCell. The children underwent the infusion of their own cord blood stem cells under the able supervision of world renowned physicians Dr. Joanne Kurtzberg and Dr. Jessica Sun at Duke University Medical Center, Durham, North Carolina, USA.

"Seeing Is Believing, Scan This & Watch A Miracle!"



LifeCell’s Medical Assistance Benefit Program Case Study

Background: This couple from Mumbai, Maharashtra, had double the joy of welcoming their twin babies in early January of 2014. To provide lifetime security to the unborn kids, they chose LifeCell International to preserve both the babies umbilical cord stem cells. Life took a spin when months later they discovered that one of the babies was diagnosed with Thalassemia Major. It's a blood disorder that affects life giving red blood cells that give oxygen to each of our body’s cells. This is due to lower-than-normal amounts of an oxygen-carrying protein called hemoglobin. There are 2 types of Thalassemia - Minor and Major. As Thalassemia Minor does not have any major symptoms, this couple was unaware of the fact that they both had a trait of this genetic disease. This meant that there is a high chance of Thalassemia Major being passed down to one of their kids and this fear turned reality! Doctors advised them that blood stem cell transplantation is the best treatment option. The decision of preserving both babies' cord blood stem cells at birth with LifeCell turned nothing less than a miracle! The siblings were a perfect 6/6 identical HLA match and the transplant could be performed. **On 15th February 2016, the patient underwent hematopoietic stem cell transplantation from his HLA-identical healthy brother’s cord blood as well as bone marrow stem cells. Using an HLA-identical sibling donor, survival is excellent for young children who are in a low-risk group.**

Patient’s Age: 2 Years
Gender: Male
Disease: Thalassemia Major
Year of Enrollment: December 2013
Date Of Sample Storage: January, 2014
Date Of Sample Release: 31st January, 2016
Date Of Transplantation: 15th February, 2016
Transplant Center: Narayana Hrudayalaya Health City, Bengaluru, Karnataka, India
Name Of Transplant Physician: Dr. Sunil Bhat, Consultant & Head of Paediatric Haematology, Oncology and Bone Marrow Transplantation Center
Type of Transplant: Related Allogenic (‘Twins’ Siblings)
HLA Matching: 6/6 (100%)

LifeCell’s Medical Assistance Benefit Program: Since the patient’s disease was diagnosed after the enrollment date (as per the Client Agreement), the family was eligible to avail this benefit program. INR 10 lakhs was transferred to the transplant facility’s bank account almost two weeks prior to transplantation.

| Remitter Account Number | Beneficiary | Bank Product | IFSC Code | Beneficiary Account Number | Amount | Inst Date | UTR Sr No | Status |
|-------------------------|------------------------------|--------------|-------------|----------------------------|---------|------------|------------------|--------------------|
| XXXXXXXX | Narayana Hrudayalaya Pvt Ltd | NEFT | HDFC0000549 | XXXXXXXXXX | 1000000 | 02/02/2016 | KKBKH16033XXXXXX | Presented and Paid |

Promises..Delivered

LifeCell’s Benefit Program Continues Spreading Smiles

From: Manik [redacted]
Sent: 04 February 2015 15:21
To: Dr.Paramjit Singh Dhot
Subject: Re: Wiskott Aldrich report Centogene: [redacted]

Dr Dhot

Thank you so much for your cooperation. I am short of words to explain how much this noble gesture from your MD and your organisation means to me.

As you have correctly mentioned, we have taken [redacted] to CMC vellore and i was in contact with Dr Revathi Raj also at Apollo Chennai. After consultation with many medical professionals, we decided to go with Dr Satyendra Katewas treatment through BMT.

So we have planned the BMT in first week of March and i will keep you posted on the developments.

We are depositing money this week for the TCR ALPHA BETA receptor kit which will be needed for Haplo transplant under Dr Satyendra Katewa at Fortis, Gurgon.

Please let me know when can the financial assistance from LIFECELL would come in as we would need the money in next 2-3 weeks.

My family is so thankful to you and you have acted like an angel for us, which we will always remember through our lifetime.

Please give my best regards and thanks to your MD who has given us tremendous support we were badly in need for.

I will stay connected and keep you udated.

On humanitarian grounds, LifeCell supported this family with INR 10 lakhs to offset the stem cell transplantation related expenses.

Because We Care

Medical Assistance Beneficiaries - Client's Eligible As Per The Agreement

| Sr. No. | Retrieval Number | Enrolling City & State | Type Of Medical Condition / Diagnosis | Date Of Credit | Total Amount Credited To Client / Hospital (INR) | Type Of Banking |
|---------|------------------|--------------------------|---|----------------------------------|--|-------------------|
| 1 | Case # 37 | Bengaluru, Karnataka | Spastic Cerebral Palsy (US FDA Approved Clinical Trial) | 26 th July, 2015 | 500000 | Private Banking |
| 2 | Case # 40 | Mumbai, Maharashtra | Thalassemia Major | 2 nd February, 2016 | 1000000 | Private Banking |
| 3 | Case # 47 | Kolkata, West Bengal | Autism Spectrum Disorder | 31 st July, 2017 | 500000 | Private Banking |
| 4 | CryoSave Client | Allahabad, Uttar Pradesh | Thalassemia Major | 18 th September, 2019 | 1000000 | Private Banking |
| 5 | Not Applicable | Surat, Gujarat | Thalassemia Major | 3 rd January, 2020 | 1301448 | Community Banking |
| | | | | | INR 43,01,448 | |

*Not Applicable - Since The Stored CBU With LifeCell Was Not Used For This Stem Cell Transplantation

Medical Assistance Beneficiaries - Client's Eligible As Per The Agreement

| Type Of Transplantation / Infusion | Case Description | Name Of Treating Doctor & Hospital |
|------------------------------------|--|---|
| Autologous | Client's Child Underwent Own Cord Blood Infusion For Treatment of Cerebral Palsy. This Was A Sponsored Clinical Trial, So Client Did Not Have To Pay Any Amount For The Treatment. The Monetary Support Was Provided For Other Related Expenses. | Dr. Jessica M. Sun, Duke University Medical Center, Durham, North Carolina, USA |
| Allogeneic | Cord Blood unit of one of the Twin Babies was 6/6 full match with the sibling patient and was Retrieved for conducting blood stem cell transplantaion along with bone marrow of the same donor. As per their Agreement, the patient was eligible for upto INR 10 lakh to offset transplant related expenses. They received full reimbursement. | Dr. Sunil Bhat, Narayana Hrudayalaya Health City, Bengaluru, Karnataka, India |
| Autologous | Client's Child Underwent Own Cord Blood Infusion For Treatment of Autism Spectrum Disorder. This Was A Sponsored Clinical Trial, So Client Did Not Have To Pay Any Amount For The Treatment. The Monetary Support Was Provided For Other Related Expenses. | Dr. Jessica M. Sun, Duke University Medical Center, Durham, North Carolina, USA |
| Allogeneic | Younger sibling's matching cord blood unit was used for blood stem cell transplantation along with bone marrow stem cells for treating the elder child for Thalassemia Major. This is a CryoSave Client and hence, LifeCell supported the stem cell transplantation cost. | Dr. Gaurav Kharya, Indraprastha Apollo Hospital, Delhi, India |
| Allogeneic | Client's baby whose cord blood stem cells were preserved with us had undergone a bone marrow transplantation for Thalassemia Major Using Her Father's 10/10 HLA Matching Stem Cells (Rarest Of Rare Case!) | Dr. Revathi Raj, Apollo Speciality Hospital, Chennai, Tamil Nadu, India |

Medical Assistance Beneficiaries
On Humanitarian Grounds Via LifeCell Foundation

| Sr. No. | Retrieval Number | Enrolling City & State | Type Of Medical Condition / Diagnosis | Date Of Credit | Total Amount Credited To Client / Hospital (INR) | Type Of Banking |
|---------|------------------|--------------------------------------|--|----------------------------------|--|-------------------|
| 1 | Case # 8 | Coimbatore, Tamil Nadu | Thalassemia Major | 1 st March, 2009 | 1200000 | Private Banking |
| 2 | Case # 32 | Noida, Uttar Pradesh | Thalassemia Major | 26 th September, 2014 | 200000 | Private Banking |
| 3 | Not Applicable | New Delhi | Severe Combined Immunodeficiency (SCID) | 7 th January, 2015 | 522000 | Private Banking |
| 4 | Not Applicable | Gurugram, Haryana | Wiskott–Aldrich Syndrome (WAS) | 4 th March, 2015 | 1000000 | Private Banking |
| 5 | Not Applicable | Dehradun, Uttarakhand | Thalassemia Major | 7 th April, 2015 | 300000 | Private Banking |
| 6 | Case # 41 | Bengaluru, Karnataka | Hemophagocytic Lymphohistiocytosis (HLH) | 23 rd April, 2016 | 500000 | Private Banking |
| 7 | CryoSave Client | Ludhiana, Punjab | Thalassemia Major | 14 th May 2018 | 952954 | Private Banking |
| 8 | Not Applicable | Jamtara, Jharkhand | Thalassemia Major | 5 th July, 2019 | 200000 | Private Banking |
| 9 | Case # 9 | Gurugram, Haryana | Thalassemia Major | 5 th July, 2019 | 200000 | Community Banking |
| 10 | Case # 61 | Jawali, Satara District, Maharashtra | Thalassemia Major | 22 nd January, 2020 | 250000 | Private Banking |

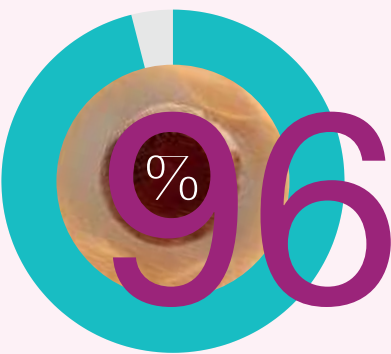
*Not Applicable - Since The Stored CBU With LifeCell Was Not Used For This Stem Cell Transplantation

Medical Assistance Beneficiaries
On Humanitarian Grounds Via LifeCell Foundation

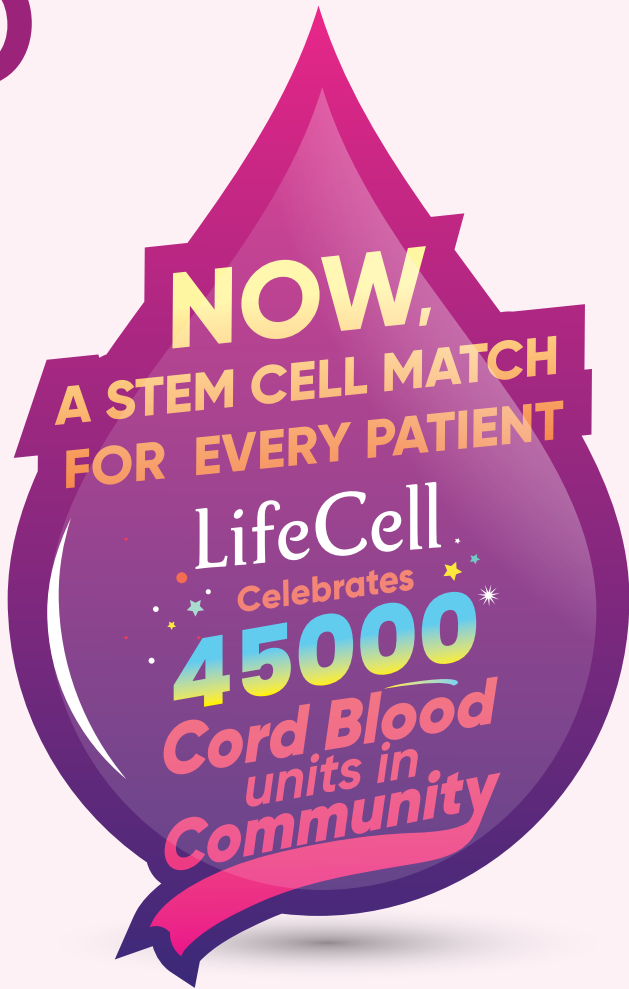
| Type Of Transplantation / Infusion | Case Description | Name Of Treating Doctor & Hospital |
|------------------------------------|--|--|
| Allogeneic | Younger Sibling's 6/6 HLA Matching Cord Blood Unit (CBU) + Bone Marrow Stem Cells Were Used For Blood Stem Cell Transplantation To Treat Elder Child With Thalassemia Major. This Client's Agreement did not had the provision for medical assistance for the baby's sibling. Financial assistance was provided through Rotary Club in Chennai. | Dr. Revathi Raj, Apollo Speciality Hospital, Chennai, Tamil Nadu, India |
| Allogeneic | Younger Sibling's 6/6 HLA Matching Cord Blood Unit + Bone Marrow Stem Cells Were Used For Blood Stem Cell Transplantation To Treat Elder Child With Thalassemia Major. | Dr. Dharma Choudhary, Dr. B. L. Kapur Memorial Hospital, New Delhi, India |
| Allogeneic | Child's own cord blood could not be used as per the transplant physician since the stem cells contained the same genetic defect. In face of no matched sibling or matched related donor availability, the patient underwent invitro TCR alpha/beta CD19 depleted, gamma/delta selected Haplo-Identical Bone Marrow Transplantation from his Father. This Client's Agreement Did Not Have The Provision For Medical Assistance For Bone Marrow / PBSCs Transplantation. | Dr. Gaurav Kharya, Dr. B. L. Kapur Memorial Hospital, New Delhi, India |
| Allogeneic | Client's Child Underwent Haploidentical Bone Marrow Stem Cell Transplantation. This Client's Agreement Did Not Have The Provision For Medical Assistance For Bone Marrow / PBSCs Transplantation. | Dr. Satyendra Katewa, Fortis Memorial Research Institute, Gurugram, Haryana, India |
| Allogeneic | Client's Child Underwent BMT Using Stem Cells From A Matching Bone Marrow Donor. This Client's Agreement Did Not Have The Provision For Medical Assistance For Bone Marrow / PBSCs Transplantation. | Rajiv Gandhi Cancer Institute and Research Center, Delhi, India |
| Allogeneic | Elder Sibling's stored CBU was Retrieved for Younger Sibling's Treatment. CBU + BM Stem Cells Of The Same Donor Were Used For The Transplantation. This Client's Agreement Did Not Have The Provision For Medical Assistance For Bone Marrow / PBSCs Transplantation. | Dr. Sunil Bhat, Narayana Hrudayalaya Health City, Bengaluru, Karnataka, India |
| Allogeneic | Younger Sibling's 6/6 HLA Matching Cord Blood Unit (CBU) Stored With CryoSave India + Bone Marrow Stem Cells Were Used For Blood Stem Cell Transplantation To Treat Elder Child With Thalassemia Major. | Dr. Sharat Damodar, Narayana Hrudayalaya Health City, Bengaluru, Karnataka, India |
| Allogeneic | Client's Child Underwent BMT Using Stem Cells From A Matching Bone Marrow Donor. This Client's Agreement Did Not Have The Provision For Medical Assistance For Bone Marrow / PBSCs Transplantation. | Dr. Revathi Raj, Apollo Speciality Hospital, Chennai, Tamil Nadu, India |
| Allogeneic | Younger Sibling's 6/6 HLA Matching Cord Blood Unit (CBU) + Bone Marrow Stem Cells Were Used For Blood Stem Cell Transplantation To Treat Elder Child With Fanconi Anemia. | Dr. Satya P. Yadav, Medanta - The Medicity Hospital, Gurugram, Haryana |
| Allogeneic | Younger Sibling's 6/6 HLA Matching Cord Blood Unit (CBU) + Bone Marrow Stem Cells Were Used For Blood Stem Cell Transplantation To Treat Elder Child With Thalassemia Major. | Dr. Ruchira Misra, NH SRCC Children's Hospital, Mumbai, Maharashtra, India |

How Community Banking Overcomes The Current Challenges Of Public Banks?

Now Every Patient in India Can Find Matching Stem Cells For Treatment



As per Indian Council Of Medical Research study, with an inventory size of **25,000** cord blood units in a bank, chances for an Indian to find matching unrelated donor cord blood stem cells is **>96%**



Currently, LifeCell's Registry has over **45,000** qualified cord blood stem cells units **(7 times of all public banks in India)**



Unlimited Retrieval of Stem Cells absolutely **Free of Cost** for Baby, Siblings, Parents and Grandparents

*Data as on February 2020
Ref: Maiers M, Halagan M, Joshi S, et al. HLA match likelihoods for Indian patients seeking unrelated donor transplantation grafts: population-based study. Lancet Haematol. 2014;1:e57-63

Welcome to the new era of stem cell banking where not just the birth of a newborn that will be celebrated, but also of that which comes attached to it at birth - the umbilical cord!

LifeCell's Community Banking Registry's HLA Matching Search Results - Encouraging Early Data

As on February 2020, we have > 45,000 Qualified Cord Blood Units (CBUs) in LifeCell's Community Banking Registry out of which ~15,000 CBUs have already been HLA Typed. We analysed this existing HLA Typing data to estimate the likelihoods of finding 6/6, 5/6 and 4/6 HLA Matched Donor Cord Blood Units from Our Registry.

The preliminary data is very encouraging when looked in tandem with the ICMR Paper that showed the probability of finding 6/6, 5/6, or 4/6 HLA-Matched CBUs in a comparable inventory size.

| Registry Size | 4 / 6 HLA Match | 5 / 6 HLA Match | 6 / 6 HLA Match |
|--|---|---|---------------------------------------|
| ICMR Paper Statistics For Bank With 25,000 Donor CBUs | 96.4 % | 72.2 % | 18.3 % |
| LifeCell Registry's 15,000 HLA Typed CBUs Analysis [Note: Our Total Registry Size Today Is > 45000 CBUs] | 98 % | 38 % | 19 % |
| Average Number Of CBUs Currently Available For Accession Per Patient From LifeCell Registry | > 50 Matched CBUs Available Per Patient | > 50 Matched CBUs Available Per Patient | > 2Matched CBUs Available Per Patient |

*Data On File As On February 2020

Example:

| Sr. No. | Age Of Patient | Patient's Diagnosis | Date Of Search | Total Number Of Matching Units Available In LifeCell's Registry Today | 4 / 6 HLA Match | 5 / 6 HLA Match | 6 / 6 HLA Match |
|----------|----------------|--------------------------|----------------|---|-----------------|-----------------|-----------------|
| Case # 1 | 3 Years | Thalassemia Major | 10-02-2020 | 448 | 392 | 50 | 6 |
| Case # 2 | 33 Years | Chronic Myeloid Leukemia | 31-01-2020 | 124 | 94 | 22 | 8 |

(P.T.O)

*Data As On February 2020.
We Matched ~50 Patients HLA Typing Reports In Our Current Database Of HLA Typed Units.



Lifecell International Private Limited
#26, Vandalur - Kelambakkam Main Road, Keelakottaiyur, Chennai - 600127

Patient Name
Age : 3Y 7M 27D Lab ID
Gender : Female DOB : 14/06/2016
Referring Doctor Report date & time : 10/02/20 7:15PM

Human Leukocyte Antigen (HLA) Matching Report

Patient Typing

| ID | HLA-A1 | HLA-A2 | HLA-B1 | HLA-B2 | HLA-C1 | HLA-C2 | HLA-DRB1 | HLA-DRB2 | HLA-DBQ1 | HLA-DBQ1 |
|----|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|
| | 11:01:01 | 33:03:01 | 40:06:01 | 44:03:02 | 07:01:01 | 15:02:01 | 07:01:01 | 15:02:01 | 02:01:01 | 06:01:01 |

Possible Match(es)

| S No | Donor ID | HLA-A1 | HLA-A2 | HLA-B1 | HLA-B2 | HLA-DRB1 | HLA-DRB2 | Match |
|------|----------|-------------|-------------|-------------|-------------|-------------|-------------|--------------|
| 1 | 34600 | 11:01:01:01 | 33:03:01:01 | 40:06:01:02 | 44:03:02 | 15:02:01:03 | 07:01:01:04 | 6 of 6 HR(2) |
| 2 | 38089 | 33:03:01:01 | 11:01:01:01 | 44:03:02 | 40:06:01:02 | 07:01:01:02 | 15:02:01:03 | 6 of 6 HR(2) |
| 3 | 32309 | 33:03:01:02 | 11:01:01:01 | 44:03:02 | 40:06:01:02 | 07:01:01:02 | 15:02:01:03 | 6 of 6 HR(2) |
| 4 | 33677 | 11:01:01:01 | 33:03:01:01 | 40:06:01:02 | 44:03:02 | 15:02:01:03 | 07:01:01:02 | 6 of 6 HR(2) |
| 5 | 4804 | 33:03:01:01 | 11:01:01:01 | 44:03:02 | 40:06:01:02 | 07:01:01:02 | 15:02:01:03 | 6 of 6 HR(2) |
| 6 | 32653 | 33:03:01:01 | 11:01:01:01 | 44:03:02 | 40:06:01:02 | 07:01:01:04 | 15:02:01:03 | 6 of 6 HR(2) |

*HR(2) :High resolution with two field match

| S No | Donor ID | Reg. Date | Donor Type | TNCC (mill) | CD34 viability (%) | CD34 Count (mill) | Blood Group |
|------|----------|------------|------------|-------------|--------------------|-------------------|-------------|
| 1 | 34600 | 26/09/2017 | CBU | 879.86 | 98.9 | 2.04 | B Positive |
| 2 | 38089 | 15/07/2017 | CBU | 788.64 | 97.7 | 2.12 | O Positive |
| 3 | 32309 | 10/11/2017 | CBU | 505.74 | 99.1 | 3.4 | B Positive |
| 4 | 33677 | 14/10/2017 | CBU | 1469.65 | 98.7 | 1.81 | O Positive |
| 5 | 4804 | 22/05/2018 | CBU | 1229.39 | 98.6 | 4.47 | O Positive |
| 6 | 32653 | 03/11/2017 | CBU | 1036.48 | 98.1 | 6.26 | O Positive |

S. S. Sita

Lab Manager- Molecular genetics
(Sureka.R)

Chirayu

Lab Director/Medical Director
(Dr.Chirayu Padhiar M.B.B.S, DCP)

Disclaimer: This is not a diagnostic test and so not be considered as a purpose of diagnosis of any diseases. The above report is meant for only understanding the match between donor and recipient.

End of report



Partnership With Cryo-Cell International, Inc., USA

World's first stem cell bank with over 28 Years of operating experience



Most Accredited

AABB | AATB | NABL | CAP | WHO-GMP | US FDA-Registered | ISO | ISBT | ISMS



Safe Transplantation Program (1st And Only Bank)

Screens every CBU before retrieval for 4000+ Genes related to inherited Disorders and Pediatric cancers at **NO EXTRA COST!**



India's Largest

World-class facilities, over 200 service centers, collections at over 6000 hospitals by >10000 gynecologists

STEM CELL TRANSPLANTATION & INFUSION RECORD

Authors

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B.Tech (Biotechnology), DBM,
Head - Learning and Development



The Ultimate Preventive
Healthcare Package To

**DETECT
PREVENT
PROTECT**

Your Baby & The Entire Family
From Thousands Of Disorders

Disclaimer:

Banking cord blood does not guarantee treatment outcomes. The use of umbilical cord stem cells to treat a medical condition is the decision of treating transplant physician based on the suitability of the treatment and whether the source of stem cells is autologous (self) or allogenic (suitable donor- siblings of the same biological parents have a 25% chance of a perfect match and a 50% chance of a partial match; biological parents have partial match). Currently, umbilical cord tissue stem cells are not approved for clinical use since they are evaluated under clinical trials and hence its use depends on the ongoing research. There is no guarantee that treatments studied in the laboratory, clinical trials and other experimental treatments (including regenerative medicine applications) shall be available in the future.

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