Save a cord. Save a life. 202020

YEAR IN REVIEW



EXPANDING APPLICATIONS FOR iTREG CELL THERAPIES

A YEAR OF CHALLENGES AND OPPORTUNITIES

The year 2020 was pivotal for the Cleveland Cord Blood Center (CCBC) as we met increasing demand for umbilical cord blood in transplantation as well as the rapidly growing cell therapy research arena.

- Investigators at the Cleveland Cord Blood Center's Research & Development Laboratory are pursuing innovative research into the generation and expansion of iTreg cells from cord blood to address a variety of autoimmune inflammation conditions and other disorders.
- Cleveland Cord Blood Center team members shared our knowledge in the U.S. and globally in areas ranging from the advancement of cord blood processing to banking in the era of COVID-19.
- Our Cell Therapy Incubator (CTI) production and distribution programs leveraged organizational and team member expertise to create new revenue stream opportunities.
- Throughout 2020, with safety precautions in place, we were able to maintain collections and meet an increasing demand for cord blood for transplantation and research.

As we make the most of the next generation of cord blood's lifesaving work, we are intensely grateful to the parents who have so generously donated their babies' cord blood to help others with critical illnesses and to make innovations in future therapies possible. In turn, we are inspired and dedicated to use this most precious gift of cord blood to help save lives and enhance health one birth at a time.



Marcie R. Finney, M.S., MBA Executive Director

THE CLEVELAND CORD BLOOD CENTER IN THE ERA OF COVID-19

5,496 Cord blood units collected near 2019 levels



1.849 Cord blood units distributed for research

Utilization rate achieved an all-time high: 62%







Certain conditions, however, are marked by inflammation where the immune system is overactive and mounts an immune response against healthy cells in the absence of infection. Addressing autoimmune inflammation with inducible T-regulatory (iTreg) cells derived from umbilical cord blood, and enhanced within a laboratory environment, offers potential to treat a wide range of autoimmune disorders. The iTreg cells replace a patient's self-attacking immune system with healthy cells that can reverse or alleviate certain autoimmune diseases.

The research into healing properties of iTreg cells has led to a potential alternative treatment for macular degeneration

Researchers at the Research & Development Laboratory are spearheading investigation into the generation and expansion of iTreg cells from CCBC's cord blood bank units. "CCBC is testing these regulatory cells for the unique properties that render them potent in suppressing inflammatory immune system response," said CCBC Research Associate Jonathan Kenyon, PhD. "Currently, pre-clinical research testing their safety and efficacy is underway."

CCBC's researchers have completed the study through proof of concept in animal testing. The team has been innovative in the manufacture of the iTreg cells, expanding them in a three-week time period under sterile conditions. The challenge was finding a way to ensure the cells divide more guickly but do not differentiate (age) during expansion. "Ex vivo expansion of the cells requires the addition of cytokines such as IL-2, which can cause the cells to differentiate (age) prematurely. Expanding the cells over a layer of stromal cells results in a positive effect, causing the cells to divide faster than normal but without aging. Their suppressive function and potency is not diminished during the expansion," said Kenyon.

In the future, the research team plans to partner with the Fred Hutchinson Cancer Research Center for an early Phase 1 clinical trial in the use of iTreg cells to address graft versus host disease (GVHD), a high priority given the life-threatening implications of GVHD. The cell therapy also shows potential to address autoimmune inflammation conditions such as Type 1 Diabetes, macular degeneration and diabetic retinopathy, among other immune-related illnesses.

Research

A healthy immune system steps up to fight infection and quiets down appropriately after resolution of the condition. This is a remarkable form of protection for the human body. Within the immune system, T-regulatory cells are assigned the task of putting the brakes on the immune response at the right time.

A HAPPY DAY SPREADS JOY





In November 2012, Emily Velez went into labor with her first child at Piedmont Hospital Atlanta. She and her husband, James, were the first to donate their baby's umbilical cord blood in Piedmont Hospital's public cord blood banking program in partnership with the Cleveland Cord Blood Center.

Recently, Emily and James welcomed their fourth child, continuing the tradition of donating cord blood when each of their children were born. "We chose a public cord blood bank over private banking. "We may never need it, but there may be a person's life we can impact," said Velez.

Velez's father has lymphoma and her grandmother passed away from lymphoma. Her stepsister survived childhood leukemia. "We're no strangers to the impact of these diseases. It made the decision to donate our babies' cord blood an easy one."

Velez describes the cord blood donation process as simple, fast and convenient. "The staff at Piedmont Hospital loves that we were the first family to donate to the Cleveland Cord Blood Center, the hospital's public cord blood bank partner. Every birth is a joyful event. It makes it that much more so when the staff is grateful you are giving this gift."

Back in 2012, the birth of the family's first son publicized umbilical cord blood donation through local media reports on the event. Their son continues to spread the word. "When we meet new people, he says, 'Hey mom, tell them I was in the news the day I was born."

CORD BLOOD	1,420	1,431
COLLECTIONS	Cleveland Clinic	Cleveland Clinic
BY HOSPITAL	Hillcrest Hospital	Fairview Hospital
1,337	1,001	307
Piedmont	Emory University	Kaiser Permanente
Atlanta Hospital	Hospital Midtown	San Francisco



SURVIVOR'S JOURNEY LEADS TO NEXT **GENERATION GIVING**

When Gail McCullough, Jr., was diagnosed with Acute Myeloid Leukemia in 2005, his doctor explained that his condition would become critical within two years and he could not survive without a bone marrow transplant. Unfortunately, despite extensive searching, no match could be found.

His physician, Dr. Mary Laughlin, suggested that the Canfield, Ohio, resident might be a good candidate for a cord blood transplant.

Since his successful cord blood transplant in 2008, Gail has enjoyed good health. He has had the privilege of walking his daughter, Brooke, down the aisle at her wedding as well as attending his son Ryan's wedding. He is now the beloved grandfather to seven, and enjoys a balance of work and leisure travel with wife, Jill.

"I was surprised at how quick and simple a cord blood transplant is, he noted. "It's enabled me to go back to a normal life without needing to take any medications related to the transplant."

Since his transplant, daughter, Brooke Anderson, of Aurora, Ohio, donated her newborn son's cord blood at Hillcrest Hospital, a Cleveland Cord Blood Center hospital partner. Daughter, Erin, of Hudson, Ohio, had previously donated the cord blood from her two babies.

"Cord blood is a great source of stem cells that can help save someone's life," he said. "They're finding more ways to use cord blood to help improve the chances of having a long life."

ABOUT 2020 CORD BLOOD RECIPIENTS

Recipients ranged in age from under 1 to 73

Race of units distributed for transplant:

58% Caucasian; 11% African American; 18% multi-race; 4% Hispanic; 9% Asian

Units distributed: U.S - 80%; internationally - 20%

Units distributed have treated a variety of diseases including:

- Acute lymphoblastic leukemia (ALL)
- Acute myelogenous leukemia (AML)
- Non-Hodgkin's lymphoma
- Myelodysplastic/ myeloproliferative disorders
- Disorders of the immune system
- Inherited disorders of metabolism
- Severe aplastic anemia



EXPANSION IN BIOTECH LEADS TO GROWTH OF CTI

In 2020, the Cleveland Cord Blood Center took a significant step forward as the Cell Therapy Incubator (CTI) implemented several production and distribution programs in support of research-related initiatives – all utilizing unused or underused cord blood units and creating new revenue streams for the organization.

The growth of CTI's client base reflects the increasing demand for well-characterized cord blood units and cord blood derived cells for research and in the biotech industry.

CTI hosted several high-specialty programs for the advancement of new cell processing technologies and products. "Among our highlights was the establishment of multiple production lines to isolate and freeze CD34+ hematopoietic stem cells from cord blood that we make available for collaborators," said Wouter Van't Hof, CEO of the Cell Therapy Incubator.

Throughout the pandemic, in conjunction with CCBC, CTI implemented a staffing paradigm that minimized the hurdles COVID-19 posed. "From an organizational perspective, we withstood the pandemic with limited impact through the expertise and diligence of our CTI staff," said Van't Hof.

The outlook for future growth of CTI looks promising as the industry expands in the areas of diversified transplant procedures and regenerative medicine. "The broader use of cells and biological tissue to treat disease will continue to drive the need for biological material derived from cord blood," noted Van't Hof. "Our success is a representation of our teamwork. We have a solid organization with the right strategy to grow and remain productive."

CLEVELAND CORD BLOOD CENTER 2008 TO 2020



NEW BOARD MEMBER BRINGS FINANCIAL EXPERTISE



The newest member of the Cleveland Cord Blood Center (CCBC) Board of Directors is Barb Drobney, the Director of Finance for LifeBanc, a nonprofit organ and tissue recovery organization. As the top finance person at LifeBanc for more than 20 years, she understands every aspect of managing an organization involved in critical health issues and research.

"I am committed to the success of organizations on whose boards I serve and strive to be of value to them," said Drobney. "The similarities between LifeBanc and CCBC surprised me. I've learned just how vital the CCBC mission is and I'm proud to be a part of this organization."

BOARD LEADS WITH INSIGHT, STABILITY

In 2020, the Cleveland Cord Blood Center leadership team, together with the Board of Directors, developed and launched new strategies for the organization's next generation of lifesaving work.

"The Board of Directors worked hand in hand with CCBC's leadership team to identify next gen priorities. Using SWOT (strengths/weakness/opportunities/ threats) analysis, our work together is focused on the accomplishment of those priorities," said board member Barb Drobney.

"As a board, we endeavor to help the organization find and allocate resources, bringing fresh ideas to the table," she concluded.



OPERATING RESERVES BECOME A PRIORITY

The impact of COVID-19 on many nonprofit organizations made one strategic initiative take on added importance during 2020 – the establishment of operating reserves to rely on when events occur outside of CCBC's control.

"Operating reserves are not only valuable for the financial side of the organization. They provide peace of mind for the management team," noted Drobney. "Many nonprofit entities live day-to-day and are unable to cover budget increases or losses during unanticipated events. The strategic initiative to build CCBC's operating reserves will provide value when they need it most."

FINANCIAL CONTRIBUTIONS

Your contribution will support the **Cleveland Cord Blood Center's work** in helping to ensure good matches for a diverse cross-section of patients. Your support will also help continue our innovative research in the development of stem cell treatments to address a variety of unmet medical needs.

TO CONTRIBUTE, CONTACT:

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Mission:	We are advancing umbilical cord blood cell therapy treatments: saving lives, enhancing health, and expanding knowledge one birth at a time.
Vision:	A world in which cord blood therapies enhance quality of life for all.
Values:	Quality. Collaboration. Innovation. Leadership. Compassion. Integrity.

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LEADERSHIP

Mary J. Laughlin, M.D., *Founder and Medical Director* Marcie R. Finney, M.S., MBA, *Executive Director* Wouter J. Van't Hof, Ph.D., *Director, Processing Facility and CEO, Cell Therapy Incubator*

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