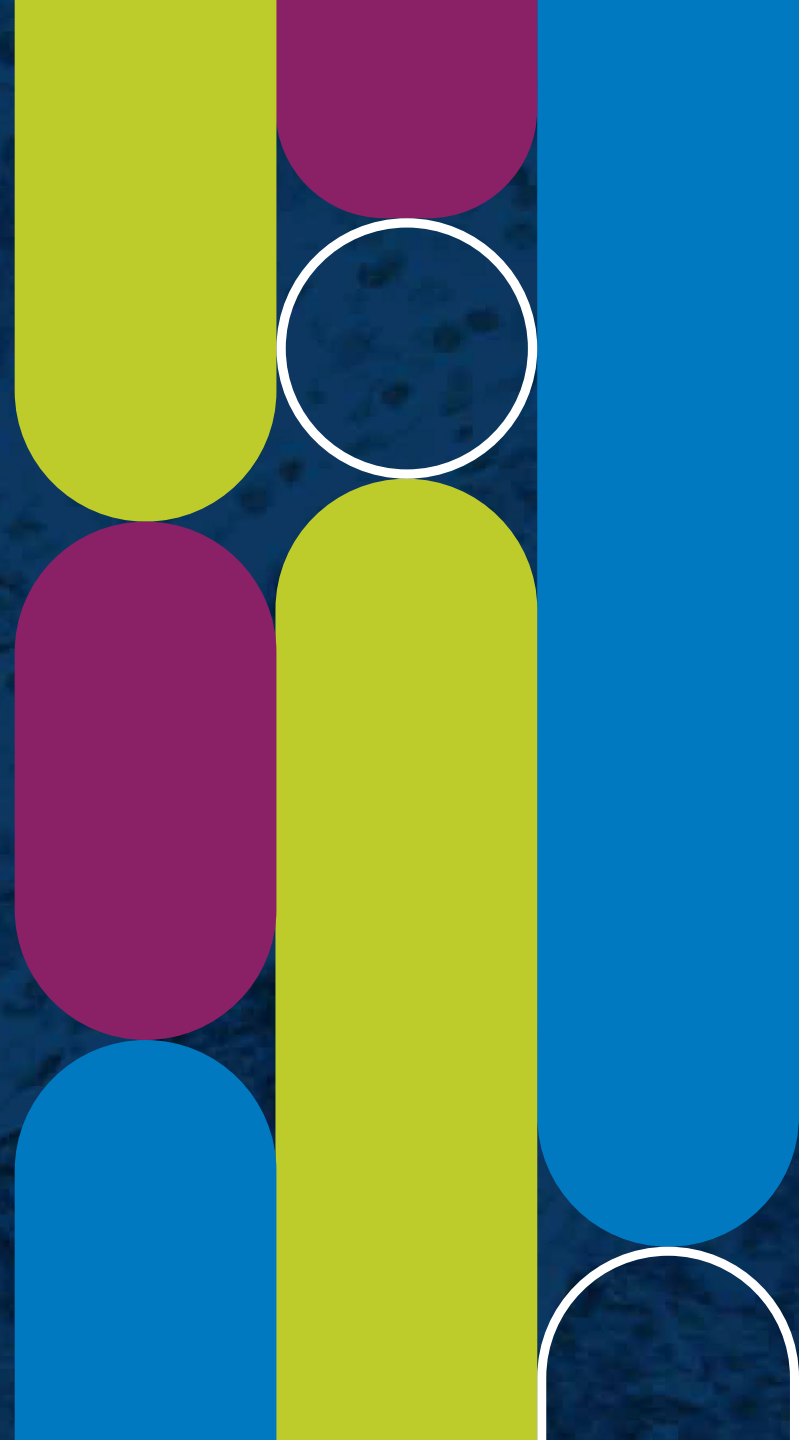




NMDP's efforts to support cord blood

Heather Stefanski, MD PhD
VP, CIBMTR and Clinical Services
NMDP



Executive Summary

NMDP is committed to ensuring research on CB is available to the community

NMDP is committed to providing CB for cell and gene therapy developers

NMDP is committed to educating healthcare providers and stakeholders about CB and best practices

NMDP is committed to CB being part of the future cell therapy landscape

Agenda

- Inventory
- Program Enhancements
- Selection Guidelines and CIBMTR proposal to address the guidelines
- Data Sets from CIBMTR
- Immersion Program
- Consultation Program
- Expanded Cord Blood Program
- CBB Alliance
- Future directions: Implementation of BMT CTN trial 1702 to pivot to alternative donors

Cord Blood Inventory & Utilization

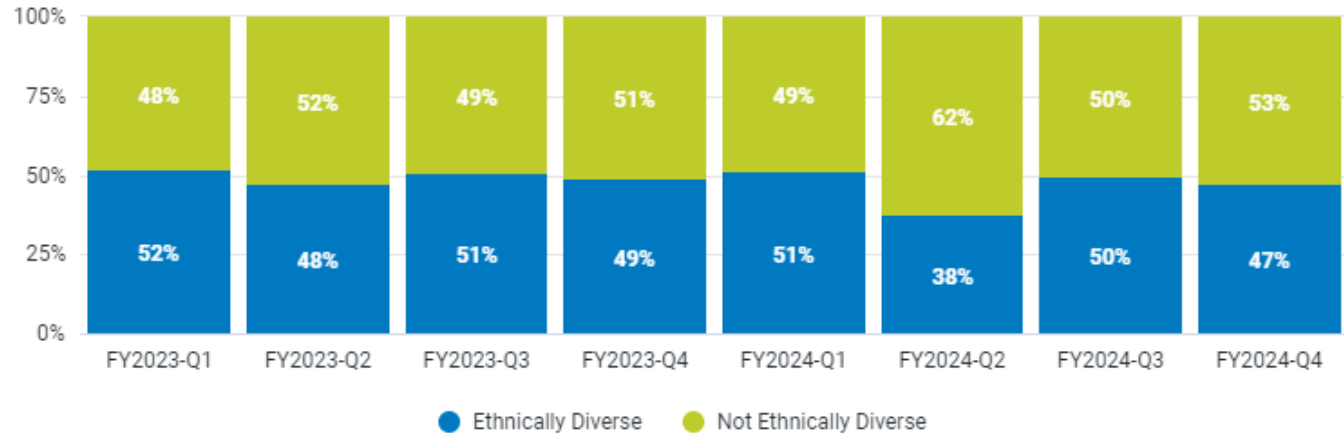
*Diversity in Supply &
Demand*

CBUs fulfill an unmet need for ethnically diverse patient

CBU Domestic Patient Ethnic Diversity

In the last 8 Quarters, 50% of US Domestic Patients receiving CB were Ethnically Diverse

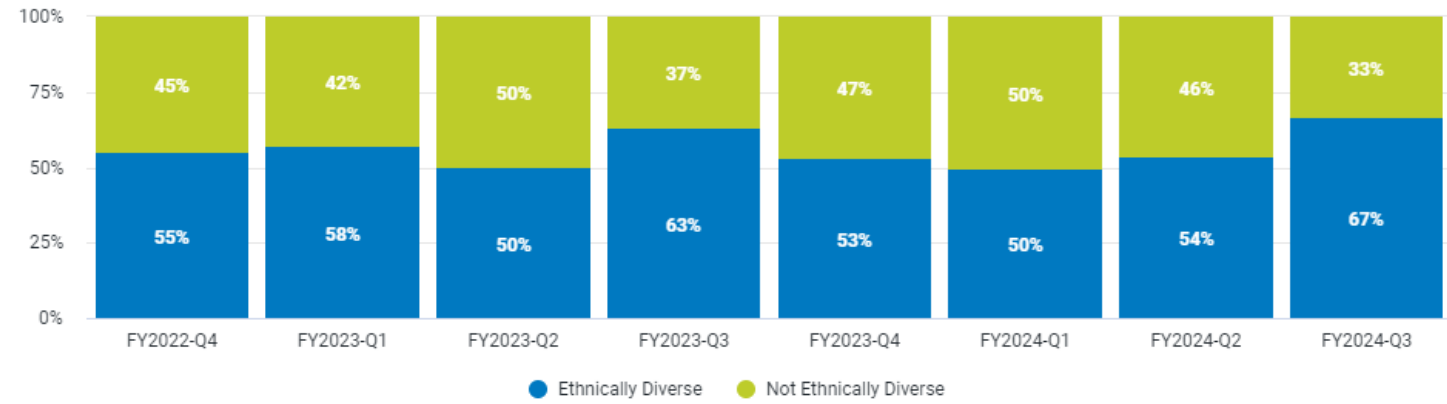
Ethnic Diversity of Patients with CBU Shipments
 > Shows percent of patients with a CBU shipment per quarter who are Ethnically Diverse. Patients with a race group of White or Unknown are classified as Not Ethnically Diverse.



Shipped Domestic CBU Ethnic Diversity

In the last 8 Quarters, 56% of US Domestic CBUs Shipped were Ethnically Diverse

CBUs Shipped by Quarter and CBU Ethnic Diversity
 Percent of shipped domestic CBUs that are ethnically diverse. Includes scheduled shipments through current quarter.



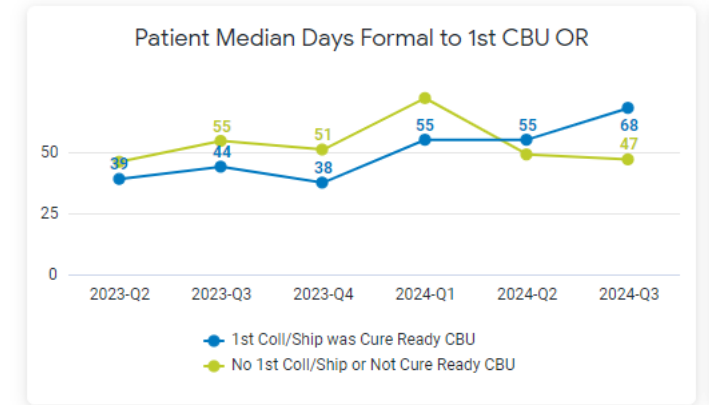
Cure-Ready CBUs

Cure-Ready designation went into effect on 10/26/2020.

High-resolution confirmatory typing at 6 loci (-A, -B, -C, -DRB1, -DPB1 and -DQB1,) completed & release/potency testing completed/passed in accordance with the cord blood bank protocols.

6,671
C-R CBUs

265 Shipped



Currently **2%** of
Domestic CBU Inventory

146 (55%) C-R Shipped = ED
119 (45%) C-R Shipped = Non-ED

Median Days Patient moves from
Formal Search to 1st CBU Order

32 Days C-R CBUs
49 Days Non-C-R CBUs

NMDP

Cord Blood Program Recent Initiatives

Operational Support & Improvements

Member CBB Survey
Enhancements

Affiliated CBB Survey
Overhaul

CBU Practice Unit
Process
Improvements &
Awareness

Bi-Annual Continuous
Performance
Improvements Report
Rebuild

OB Training Process
Enhancements

CB Immersion
Program Interactive
Training Module
Creation

CBB Recruitment
Collateral Updates
and Re-Brand

Cord Blood Bank
Alliance Established

System Enhancements

NCBI Funding
Process Automation
& Reporting
Improvements

CBB Data Reporting
Dashboard Rebuild

MatchSource CB
Search & Selection
Enhancements

CordSource
Application
Enhancements and
Maintenance

Network Website TC
Cord Blood
Transplant Hub
Created

Cord Blood Data Set
Established Public
Availability

CBU Cure-Ready
Concept Established
and Implemented

CordSource
Interactive Training
User Guide Rebuild

Relationship Management

CBB Partner
Gatherings
Quarterly

WMDA CB
Steering
Committee
Involvement

Anthony Nolan
Partnership

CBB Contingency
Guidelines paper
(Collaboration w/
CB community)

Shipping Best
Practices paper
(Collaboration w/
CB Community)

World Cord Blood
Day Annual
Support

Cord Blood
Awareness Month
Annual Support

ONE Forum Conf.
Sessions

Cord Blood
Connect Conf.
Presence

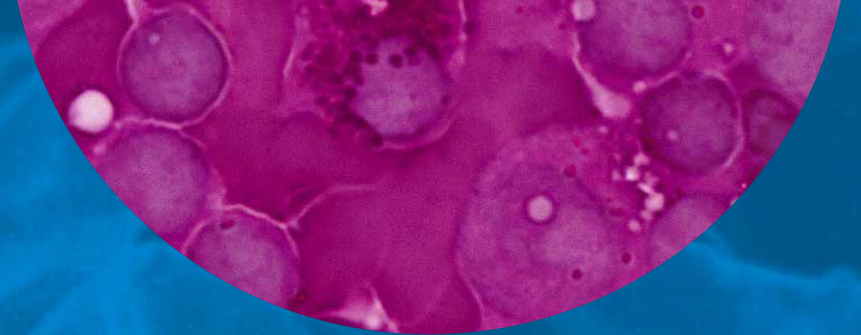
CIBMTR CB Data
Working Group
Involvement

CB HRSA
Deliverable
Ownership

CBU Selection Guidelines



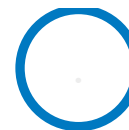
The guidelines created jointly with the NMDP Histocompatibility Advisory Group, which consists of key opinion leaders in immunogenetics and HCT are based on current and relevant data supporting optimal HLA donor–recipient matching criteria and other factors affecting graft selection.



Guidelines

	Guidelines
<p>Bank practices</p> <p>Attached segment identity testing Use of RBC-replete units*† Cryovolume‡ Year of cryopreservation</p> <p>Bank location Bank accreditation and/or licensure</p>	<p>Mandatory</p> <p>Not recommended</p> <p>Should be considered, especially if the unit is to be diluted post thaw</p> <p>More recent units may be linked to optimal banking practices depending on the bank</p> <p>Domestic or international units fulfilling selection criteria</p> <p>Should be considered</p>
<p>HLA match</p> <p>Resolution of HLA typing</p> <p>Donor–recipient HLA match</p> <p>Unit–unit HLA match for double unit CBT</p> <p>Avoidance of units against which recipient has DSA§</p>	<p>Minimum of 8 high-resolution (HLA-A, HLA-B, HLA-C, and HLA-DRB1) for both patient and CB unit</p> <p>≥4/6 HLA-A and HLA-B antigen, HLA-DRB1 high-resolution (traditional match), and ≥4/8 high-resolution match (some centers investigating use of 4/6 and 3/8 units if adequate dose)</p> <p>Not required</p> <p>Conflicting results in hematological malignancies; avoid if nonmalignant diagnosis</p>
<p>Cryopreserved cell dose ¶#</p> <p>Single-unit CBT: minimum dose/kg</p> <p>Double-unit CBT: minimum dose/kg per unit</p>	<p>TNC $\geq 2.5 \times 10^7/\text{kg}$ and CD34⁺ cells $\geq 1.5 \times 10^5/\text{kg}$ (some centers recommend higher CD34⁺ dose as minimum)</p> <p>TNC $1.5 \times 10^7/\text{kg}$ for each unit and CD34⁺ cells $\geq 1.0 \times 10^5/\text{kg}$ for each unit (some centers recommend higher CD34⁺ doses for each unit as minimum)</p>

Dehn et al, 2019



Search Results 6 Filters Applied Search Results: Current Go To Run Search Cart

ABAMANZX, RBAMANZX / 547-483-1 Phenotype 1 (Actual) Local ID U5551349 TC ID 501 Patient Status FRML
 Age 47 Sex M ABO/RhD B+ CMV Positive A 02:01:01 B 44:02:01 (T) C 05:01:01 DRB1 11:04:01 DQB1 03:01:01 DPB1 04:HJMR (L) Transplant Timeline Pending, Case M... As of SEP 21 2023
 03:01:01 13:02:01 (T) 06:02:01 07:01:01 02:02:01 04:FNV5 (L)

Filter 8 Find Columns OPL

Clear All Filters

Filter by Cord Selection Guidelines

Single Unit Transplant

Double Unit Transplant

Sort by Cord Selection Guidelines

CD34+ then 8 Allele Match then TNC

> Lists

> Match Preference (4)

Match Criteria - 6/6

Match Criteria - 5/6

Match Criteria - 4/6

Likelihood - 4/8 75%

> Cord Basics (4)

Minimum TNC - 2.5 TNC/kg

Minimum CD34+ - 1.5 CD34+/kg

RBC Reduced - Yes

RBC Reduced - Unknown

> ABO

Cancel Apply

Cords Classic view Sort by 6 Traditional then TNC then CD34+ Request Unit Report

Export/Unp	OPL	Ref	Status	List	ID	TNC/kg	TNC	Prev CT	DOB	Final Prod Vol	MCat x/8	MCat x/6	Pr(n) of 8 (%)	Pr(n) of 6 (%)	A	B	C
																<ul style="list-style-type: none"> L 44:EZR A 13:02 	<ul style="list-style-type: none"> M 02:AVZMT P 06:AXBZF
																<ul style="list-style-type: none"> P 44:BZEGU P 13:BZEFH 	<ul style="list-style-type: none"> P 05:01:01G P 06:02:01G
																<ul style="list-style-type: none"> P 44:DMKKD P 13:CAVKS 	<ul style="list-style-type: none"> P 05:DMKKT P 06:DMFHJ
																<ul style="list-style-type: none"> P 44:BKEVU P 13:ABWRB 	<ul style="list-style-type: none"> P 05:ABWZB P 06:ABWZG
																<ul style="list-style-type: none"> P 44:BKEVU P 13:ABWRB 	<ul style="list-style-type: none"> P 05:ABWZB P 06:ABWZG
																<ul style="list-style-type: none"> P 44:ABHDM M 35:ZMJC 	<ul style="list-style-type: none"> P 05:AYJRX M 04:BEHBB

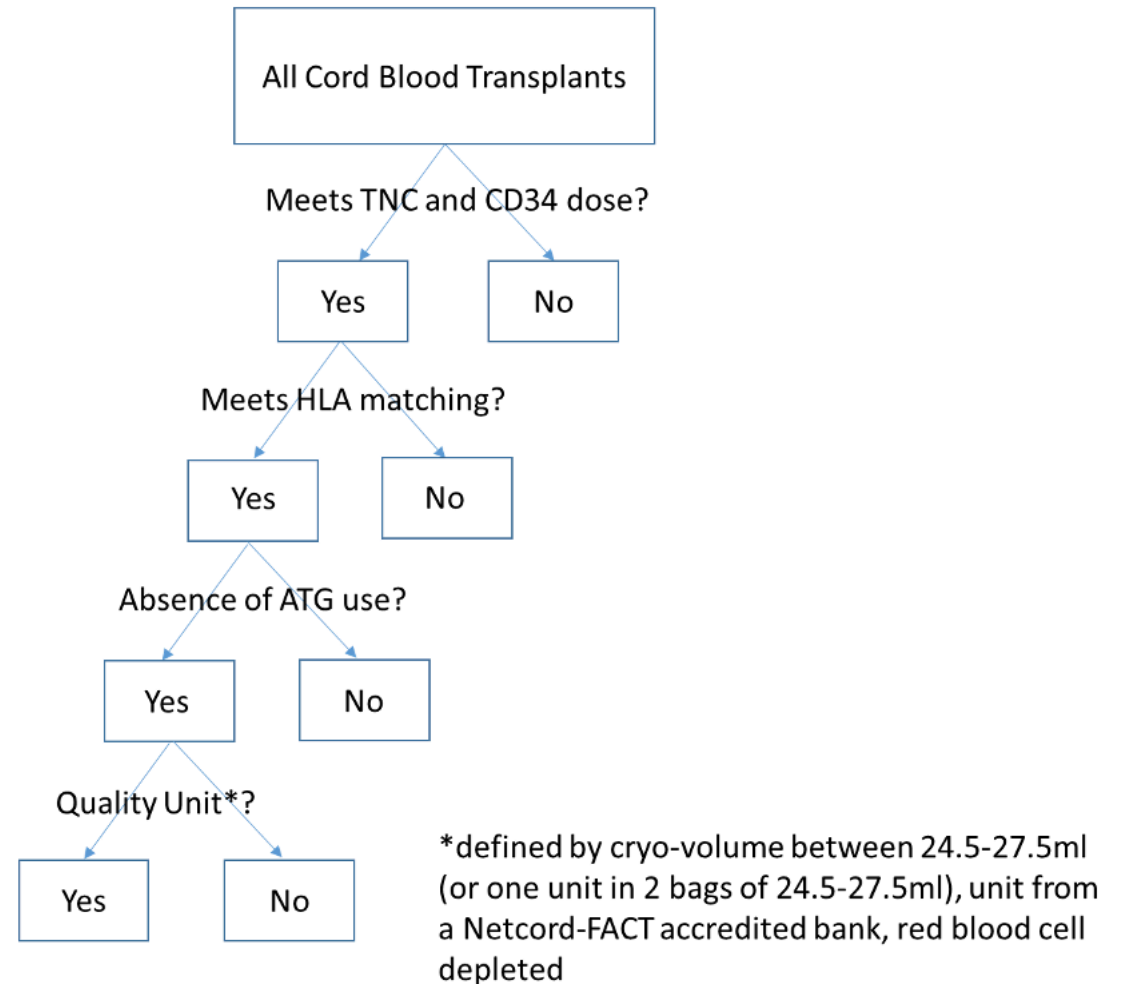
Cord Selection

- Cell Dose – TNC and CD34
- HLA Matching
- Quality Characteristics
- International vs Domestic – both are fast!



CIBMTR Immunobiology Proposal – Metheny et al.

To compare the overall survival (primary outcome), non-relapse mortality, relapse rate and disease free survival (at 1, 3, & 5 years post-transplant) between cord blood transplants (both double and single) that adhered to cord blood guidelines (TNC dose, CD34 dose, HLA matching, and avoidance of ATG) with cord blood transplants that did not adhere to cord blood guidelines.





CIBMTR Cord Blood Reports



Cord Blood Quarterly Quality Reports

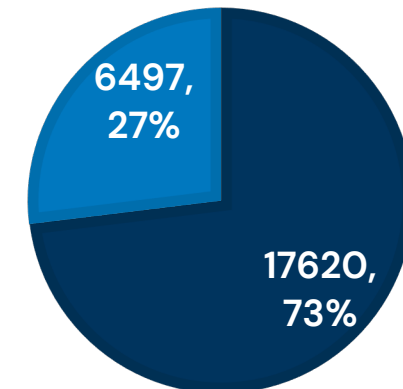
- Infusion dates (all)
- Number of cord blood units infused (includes cord blood infusions facilitated by NMDP for which infusions occurred more than 3 months ago)

Total: 24,117

- US HCT transplant centers: 17,620
- Non-US HCT transplant centers: 6,497

CORD BLOOD INFUSIONS

- US HCT Transplants
- Non-US HCT Transplants



Cord Blood Quality Report Fields

- Identifiers
- Patient Demographics
- Disease
- Transplant Characteristics
- Product Characteristics
- Outcomes



Cord Blood De-Identified Dataset

- Dataset is limited to a fixed set of variables
- Fields: 213 fields in De-Identified Reports
- Infusion dates: 1999 – Current
- Only includes data on consented records

- Reports
 - Cord Blood De-Identified Quality Dataset
 - Cord Blood Patient Level Dataset
 - Data Dictionary

Cord Blood Data Set

Identifiers

**Patient
Demographics**

Disease

**Transplant
Characteristics**

**Product
Characteristics**

Outcomes

Proposals

- Once approved by CIBMTR Leadership, access to the De-Identified dataset will be granted.
- All proposed projects using this resource will be shared with the Cord Blood Advisory Group (CBAG).
- At the 6 month & 1-year timepoint, CIBMTR will follow up to learn of the study progress and outcomes.
- We have received 4 proposals for the dataset



Cord Blood Transplant Immersion Program

Supported by Health Resources Services Administration (HRSA)



Cord Blood Transplant Immersion Program

We are proud to announce the first Cord Blood Transplant Immersion Program!

- Two junior physician mentees, one specializing in adult transplant and one specializing in pediatric, will participate in this inaugural program by spending two weeks on-site learning from an expert mentor
- Mentees will complete educational modules created by leaders in the cord blood community
- This program is intended to help establish the next generation of well-trained and competent transplant clinicians, improving quality of practice and ultimately patient outcomes of cord blood transplantation

The Cord Blood Immersion Program has been made possible through the support of the Health Resources Services Administration (HRSA) and NMDP.



Identifying potential mentees

- Transplant centers were categorized based on patient population and cord blood usage
- Special focus was given to centers with patient populations that had high rates of pediatric and/or racially and ethnically diverse patients, as well as those with a low volume of cord blood use
- NMDP Clinical Operations Partners from these centers were provided with application materials and talking points and reached out to program directors
- NMDP posted application materials on X and LinkedIn social media channels
- Received six qualified applicants; could select two for participation

The Cord Blood Immersion Program has been made possible through the support of the Health Resources Services Administration (HRSA) and NMDP.

