

Collecting Umbilical Cord Blood



Dr. Michael T. Medchill, MD

Consent

- **Verify** patient has been consented and meets general eligibility requirements
 - 18+ years old
 - Single gestation (no multiples)
 - 36+ weeks
 - Good health history
 - May verbally consent the patient

(Specific eligibility questions should be directed to coordinator or blood bank.)

Preparing for Collection

- Collection Supplies:
 - Collection Bag
 - 2 Blue Clamps
 - Needle Guard
 - Sterile Adapter (C/S *only*)

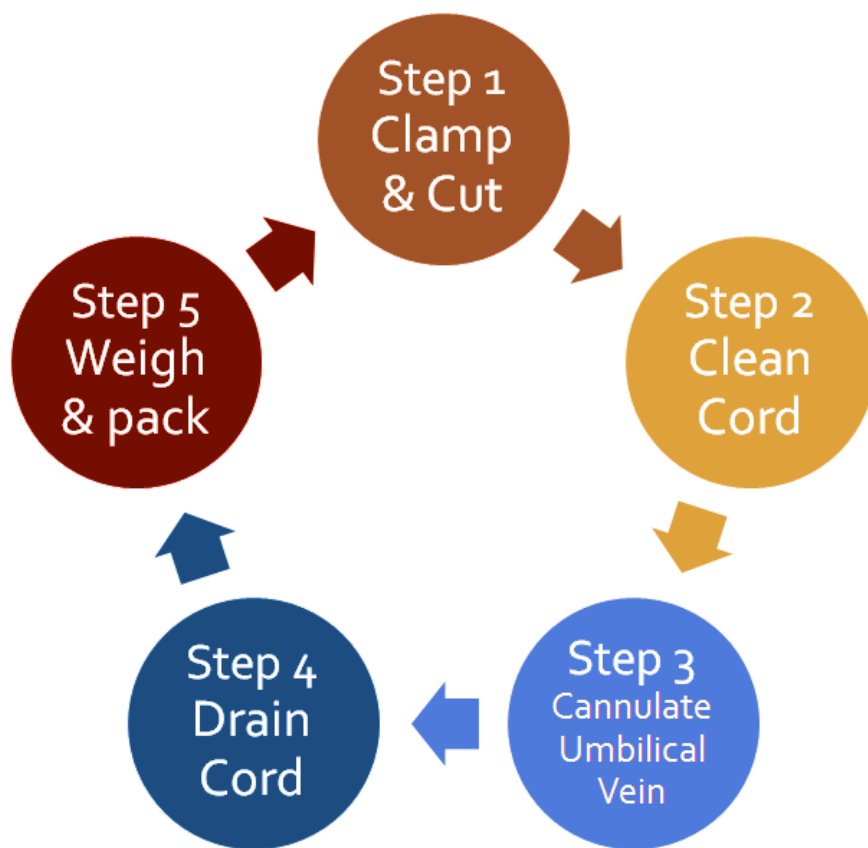


The sterile adapter is the only piece that should be placed in a “sterile field”.

Organize your supplies on the delivery table so they are easily accessible.



How Umbilical Cord Blood is Collected



- Baby is not touched
- The mom and baby are not harmed

Deliver the Baby / Clamp the Cord



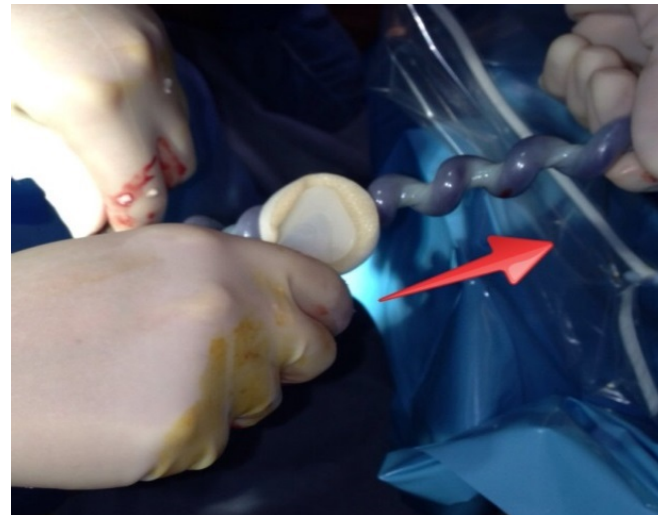
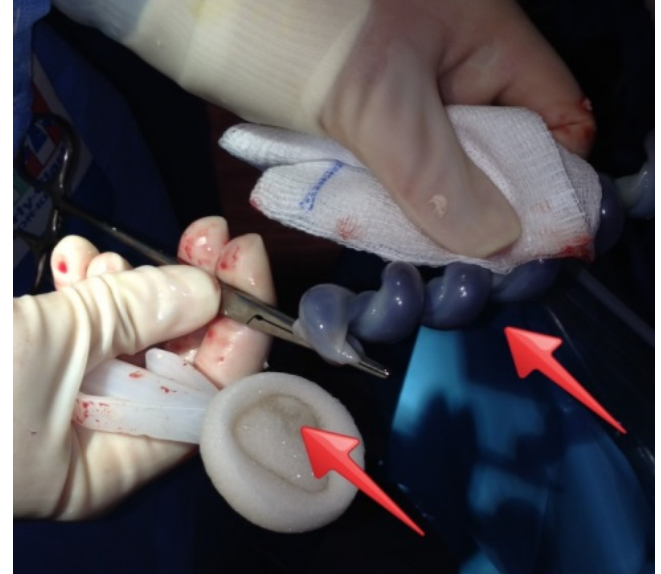
Following the birth of the baby and prior to delivery of placenta: Place **two** surgical clamps or cord clamps on the cord as close as possible to the baby and cut between them.



Step 1
Clamp
& Cut

Cleaning the Umbilical Cord

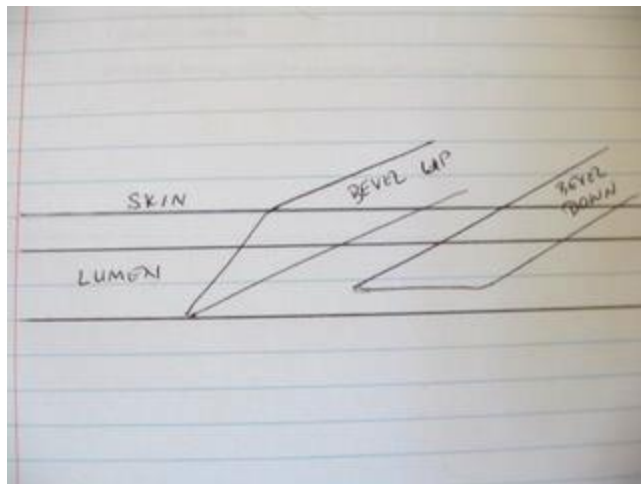
- Select a cord venipuncture site at the lowest possible point.
- Wipe the cord with gauze or sterile towel to remove excess fluids.
- Clean with Chloraprep swab



Step 2
Clean
Cord

Cannulation

Cannulate the umbilical vein (bevel down) with the needle attached to the cord blood bag.



Step 3
Cannulate
Umbilical
Vein



In a Cesarean Section the physician cannulates with the needle on a sterile adapter and CB personnel or other OR assistants can connect the blood bag needle into the sterile adaptor.

Then...the **waiting** game begins

- Stabilize the cord
- Allow sufficient time for **gravity** to empty
- Ensure blood bag is lower
- Gently rock the bag to mix with anticoagulant
- Wait until blood flow ceases and cord appears blanched

Step 4
Drain
Cord



Volume is Key

Insufficient



Sufficient



Optimal



IMPORTANT – Collect as much cord blood as possible.

Insufficient volume will render the cord blood unit unusable for stem cell transplant. Larger volume collections mean a larger volume of stem cells collected. Units containing a high volume of cells are optimal for transplantation.

What's My Big Secret?



Other Blood Samples

If the hospital protocol requires collecting a neonatal sample for ABO typing or cord gas pH testing:

- Take the smallest sample necessary for gas pH testing
- ABO sample can be obtained after CB collected
- Less than 3ml blood volume necessary

Not every umbilical
cord has an optimal
amount of blood, **BUT**
most often there is **a**
lot of blood left
behind.

**"IF YOU'RE LUCKY
ENOUGH TO GET A SECOND
CHANCE AT SOMETHING,
DON'T WASTE IT."**

~UNKNOWN

Maximizing the Collection

- Once the blood flow has seemed to stop then re-clamp the cord just above your insertion site.
- Remove the needle and carefully readjust.
- Milk the cord in an upward motion and re-clamp higher.



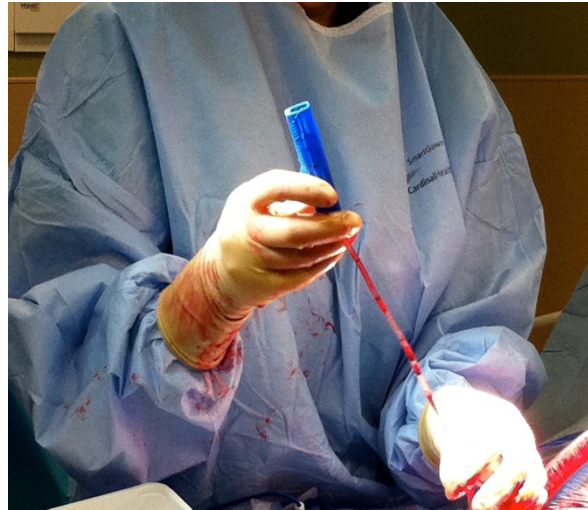
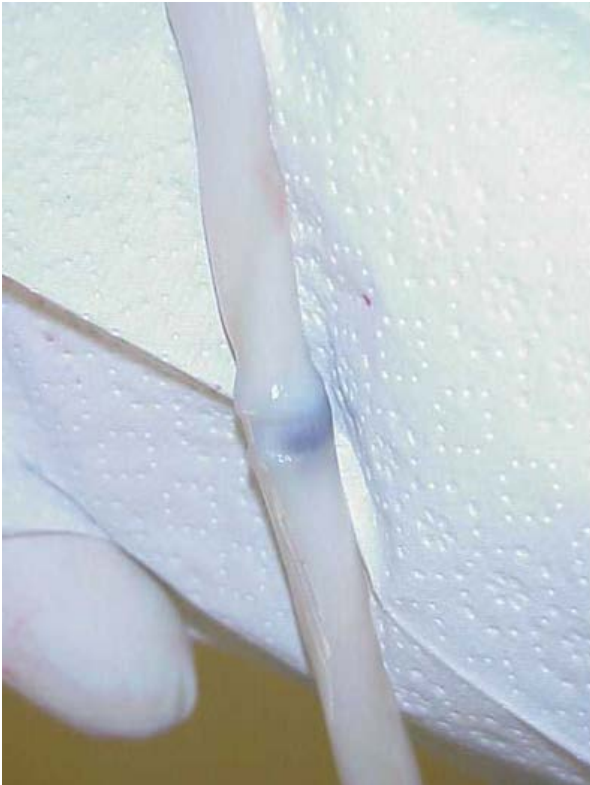
Maximizing the Collection

- Once the placenta separates and begins to come through the vaginal canal there is another gush of blood that is pushed into the cord.
- Repeat the process of cleaning the cord (with new gauze and Chloraprep) and re-cannulate just above your clamp when you see the cord fill again.



Finishing the Collection

Wait until blood flow into bag ceases and carefully remove needle from cord.



Once blood has drained into bag, immediately cover the needle with the provided needle guard, strip and clamp the tubing, tie off the tubing above the clamps and cut off and dispose of remaining tubing with needle attached according to hospital's safe needle disposal procedures.



Finishing the Collection



The consenters take over and finish the packing and shipping.

Step 5
Weigh
& pack

Cord Blood Donation--

It's the chance to

GIVE LIFE TWICE!



**KEEP
CALM
AND
SAVE
LIVES**



Questions?

2016 Saving Lives

*The Clinical /Research Regulatory
Experience in Cord Blood Banking:
Collection to Infusion*

AZ CB Collected = 5669

AZ CB Transplanted = 31



University of Colorado
Cord Blood Bank

Sharon Miller
UCCBB Director of Regulatory Affairs

FDA and the Public Consent and Collection Team



Guidance for Industry

Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)

Additional copies of this guidance are available from the Office of Communication, Training and Manufacturers Assistance (HFM-40), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, or by calling 1-800-835-4709 or 301-827-1800, or from the Internet at <http://www.fda.gov/cber/guidelines.htm>.

For questions on the content of this guidance, contact the Division of Human Tissues, Office of Cellular, Tissue and Gene Therapies at 301-827-2002.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
August 2007

Public Banking to Anonymous Unrelated Recipients (Allogeneic) or Private Banking for Autologous use?

- Risk Based FDA Regulation...less regulation for autologous/ self (and first degree relative) banking



FDA Biologic License for Injectable Drugs (Public Cord Blood)

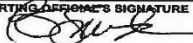
- Off- label Use: Injecting a Licensed Cord blood for purposes other than *“For use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment.”*
- IND Research Use: required for injection of an unlicensed minimally manipulated cord blood (NMDP) or more than minimally manipulated CB.

Historic 1998 - 2012 UCCBB Indications for Use- Diagnosis of Recipients Infused (Prior to licensure)

Indications / Diagnosis	# Recipients	% of total infused
Acute Myelocytic Leukemia (AML) (JML,JMML)	161	30%
Acute Lymphocytic Leukemia (ALL)	130	24%
Mucopolysaccharoidosis (MPS)	30	6%
Hodgkins Lymphoma (HLH) Lymphoma	27	6%
Chronic Lymphocytic Leukemia (CLL)	15	3%
Fanconi Anemia	15	3%
Non- Hodgkins Lymphoma (NHL)	14	3%
Aplastic Anemia (AA)	11	2%
Chronic Myelogenous Leukemia (CML, JCML)	14	3%
Severe Combined Immuno Deficiency (SCID, Immunodeficiency)	14	3%
Myelodysplastic Syndrome (MDS)	8	2%
Hemophagocytic Lymphohistocytosis	8	2%
Wiscott Aldrich Syndrome (WAS)	5	1%
Biphenotypic Leukemia	3	1%
Hurler's Syndrome	6	1%
Unknown	10	2%
Multiple Myeloma (MM)	3	1%
Neuroblastoma	3	1%
Osteopetrosis	4	1%
APL, ADL, AMT, B-Thal, Burkits, CGD, FEL, LAD, LPD, Neiman-Pick, Omens, PNH, Renal cell	2 each	<1%
Brain tumor, Breast C, CID, Krabbe, LAL ,LCL ,mantle cell, MZL, Monosomy 7, MML, PSD,RCMD, Ref Anem, sickle cell, XLP	1 each	<1%

FDA REGISTRATION: Annual Autologous and Allogeneic FDA Recovery Site HPC/Tissue Registration

See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 1/31/14

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) <i>(See reverse side for instructions)</i>		1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 3000719146	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION—FOR FDA USE ONLY VALIDATED BY FDA:30-NOV-2010 DISTRICT: Denver PRINTED BY FDA:02-NOV-2011																																																																																																																																																																																																																																																																																																																			
PART I - ESTABLISHMENT INFORMATION 3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2881 NO. _____ c. DRUG FDA 2856 NO. _____ 4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> ClinImmune Labs-Univ Colorado Cord Blood Bank and Stem Cell Laboratory 12635 E. Montview Boulevard Suite 300 Aurora, Colorado 80045 a. PHONE 303-724-0535 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY 5. ENTER CORRECTIONS TO ITEM 4 _____		PART II - PRODUCT INFORMATION 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2">Types of HCT / Ps</th> <th colspan="8">Establishment Functions</th> <th rowspan="2">11. HCT/Ps DESCRIBED IN 21 CFR 1271.19</th> <th rowspan="2">12. 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8. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> ClinImmune Labs Attn: Brian M. Freed, Ph.D. 12635 E. Montview Boulevard Suite 300 Aurora, Colorado 80045 a. PHONE 303-724-0535 EXT _____ 7. ENTER CORRECTIONS TO ITEM 6 _____ b. PHONE _____		9. U.S. AGENT a. E-MAIL _____ 9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Brian M. Freed, Ph.D. b. E-MAIL brian.freed@ucdenver.edu c. TITLE Executive Director d. DATE 7/2/14/14																																																																																																																																																																																																																																																																																																																					



ClinImmune Labs-University of Colorado Cord Blood Bank

PUBLIC Bank is the second in world to obtain:
FDA Biologic License # 1855 issued May 24, 2012

- How does licensure affect public collection sites and the teams that consent, collect, evaluate and assess donor risk?



FDA Laws and Regulations: Donor risk/eligibility, Consenting and Shipment

- The FDA has moved from the collection and processing of HPC, Cord Blood to the “*Storage, Processing and Distribution*”.
- FDA: Fresh cord blood must be stored at 15-25 °C (59-77°F)-any deviation will not be licensed.

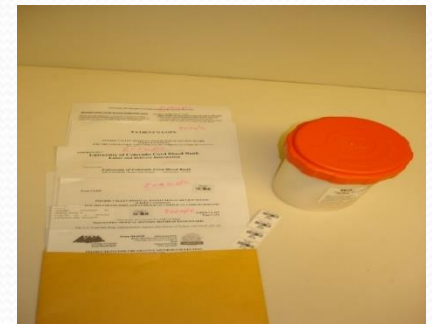


Public Consent and Collection Team

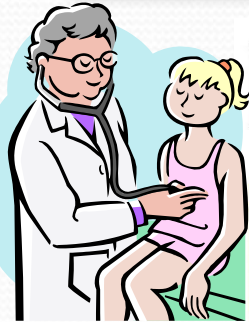
- **Since 2012 FDA biologic licensure for public banking, there is no longer a requirement to obtain IRB research review and approval for the recovery of HPC, Cord Blood waste products banked for clinical use or used as de-identified waste products for research.**
- **Although cord banking accrediting agencies (AABB, FACT) maintain review of collection hospitals, the FDA does not inspect recovery sites (Labor and Delivery decks). AABB accreditation does require a collection site inspection.**
- **Informed Donor consenting continues and option to refuse research is offered as an option. Review may still be requested for approval by the hospital IRB.**
- **The UCCBB goal is to keep it simple!**

Maternal Donor Testing for Communicable Diseases

- 21 CFR 1271.80 (b) Maternal Test sample must be collected at, or up to 7 days before or after product cord blood collection.
- Inf D Test sample dilution? >2000 ml colloids up to one hour before collection.
- 21 CFR 1271.80(c) Infectious Disease Test Kits used must be licensed!



HPC Donor Risk Assessment Screen for Communicable Diseases: History for BOTH Donor and Family Questionnaires and Hospital History and Physicals (For HPC, Cord Blood –Both maternal and baby)



NATIONAL MARROW DONOR PROGRAM

BE THE MATCH®

REVIEWED
Initials *AL* Date *12/20/11*

Cord Blood Registration:
Maternal Risk Questionnaire

Bank Use Only

9915-5314-1 NMDP CB ID	8023630	
NMDP CBU ID	Local CBU ID	
9915-5315-8 NMDP MAT ID	7023630	<i>10 12 2011</i> Today's Date
NMDP Maternal ID	Local Maternal ID	Baby's Mother's Initials

Please read questions carefully and answer to the best of your knowledge.

- Have you ever donated or attempted to donate cord blood using your current, or a different name, to this cord blood bank? Yes No
- Have you, for any reason, been deferred or refused as a blood or cord blood donor, or been told not to donate blood or cord blood? Yes No
If yes, why? _____
- Have you taken any of the following medications (check all that apply)..... Yes No
 - Insulin from cows (bovine or beef insulin) since 1980? Yes No
 - Growth hormone from human pituitary glands ever? Yes No
 - Rabies vaccination in the past year? Yes No
- In the past 8 weeks, have you had any shots or vaccinations? Yes No
If yes, please describe: _____
- In the past 12 weeks, have you had contact with someone who has received the smallpox vaccine? (Examples of contact include physical intimacy, touching the vaccination site, touching the bandages or covering of the vaccination site, or handling bedding or clothing that had been in contact with an unbandaged vaccination site.)..... Yes No
- In the past 4 months, have you experienced two or more of the following: a fever (>100.5°F or 38.06°C), headache, muscle weakness, skin rash on trunk of the body, or swollen lymph glands? If yes, which symptoms and when? Yes No
- Have you ever had any type of cancer, including leukemia?..... Yes No

National Marrow Donor Program®
Document Number: F00316V9.0
version: 04/2011

Continue on to Page 2

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NATIONAL MARROW DONOR PROGRAM

BE THE MATCH®

REVIEWED
Initials *AL* Date *12/20/11*

Cord Blood Registration:
Family Medical History Questionnaire

Bank Use Only

9915-5314-1 NMDP CB ID	8023630	
NMDP CBU ID	Local CBU ID	
9915-5315-8 NMDP MAT ID	7023630	<i>10 12 2011</i> Today's Date
NMDP Maternal ID	Local Maternal ID	Baby's Mother's Initials

Please read questions carefully and answer to the best of your knowledge.

10 12 2011 Today's Date Baby's Mother's Initials

- Were you and/or the baby's father adopted at early childhood? Yes No
 - If yes, is a family medical history available for you and/or the baby's father? Yes No
- Are you and the baby's father related, except by marriage? (e.g. first cousins) Yes No
- Did this pregnancy use either a donor egg or donor sperm? Yes No
 - If yes, is a family medical history questionnaire available for the egg or sperm donor? Yes No
- Have you had an abnormal result from a prenatal test (e.g. amniocentesis, blood test, ultrasound)? Yes No
If yes, answer the following questions. If no, skip to question 5.
 - Which test was abnormal? _____
 - What was the abnormal test result? _____
 - Was a diagnosis made? Yes No
If yes, specify diagnosis: _____
- Have you had any children who died within the first 10 years of life? Yes No
 - If yes, what was the cause? _____
- Have you ever had a stillborn child? Yes No
 - If yes, what was the cause? _____

National Marrow Donor Program®
For internal use only. Document F00323 v7.0
P0787, JUL 2011

Continue on to Page 2

Page 1 of 4

Collection Hospital FDA Regulated Donor Risk: H & P Screening Issues: It's not just infectious disease testing and it's not just the baby

- Maternal Donor Purified protein derivative (PPD) test for TB +.....Immunized (BCG) or exposure.
- Abnormal PAP test on Maternal Donor....ASCUS is OK.

Historic Abnormal PAP Grade	Collection ?	Collection-if abnormal before delivery
ASCUS	Yes	yes
AGUS	Yes if normal test before delivery	no-unless donor is stable and can be reached after six week PP result
LGSIL	Yes if normal test before delivery	no-unless donor is stable and can be reached after six week PP result
HGSIL	Yes if normal test before delivery	no-unless donor is stable and can be reached after six week PP result

- Chorioamnionitis....antibiotic treatment and maternal/baby blood cultures.
- Family History of Genetic Disease: BMS, BGP, BS, BF

Public Genetic Screening Issues

- Autoimmune disorders: Graves/ Hashimotos vs. Hyper and Hypothyroidism? DM I?

Autoimmune disorder	M	F	S	GP	A/U
Celiac Disease	R	AT	R	AT	AT
Crohn's disease or *ulcerative colitis	R	AT	R	AT	AT
Dermatomyositis	R	AT	R	AT	AT
Diabetes- insulin dependent- Type I	R	R	R	AT	AT
Goodpasture's syndrome	R	AT	R	AT	AT
Grave's disease	R	AT	R	AT	AT
Lupus (Systemic)	R	AT	R	AT	AT

- Blood disorders: ITP ? Low platelets?
- Gallbladder removed before 30?
- Sickle Cell or Thalassemia Hemoglobin for trait(homozygous) vs disease (disease). SCIDs.

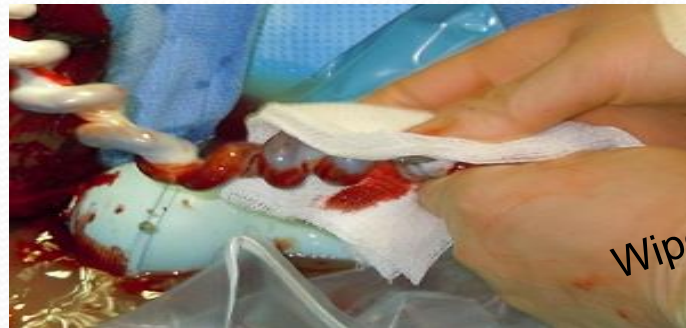
Result	Race
F + A + 17.5 % Bart's Carrier per UH Clin Chem	Asian or Pacific Isl
A+F+S 15.3% sickle cell carrier state	Hispanic
F+A+D bands present D-Punjab Trait	Hispanic
F + A + Bart's Trait bands present	Black or African Ame

Quality Sterility Prep for Cleaning the Umbilical Cord for In-Utero Collection method

- Prior to birth of the placenta, select a cord venipuncture site.
- Wipe cord with the gauze to remove excess fluid.
- Clean area with Chloroprep swab provided in kit. **Swipe up with one side of the swab and down with the other.**
- Wait 30 seconds for the Chloroprep to dry before venipuncture.

Please...

- * Do **not** allow maternal blood to contaminate venipuncture site.
- * Do **not** apply excessive traction to the cord.
- * Do **not** manually remove the placenta.



Wipe with Gauze



Swab with Chloroprep and
wait to dry!

Public Cord Blood: Collection Volume

Blood Volume (mL) = White (CD34+) and nucleated RBC

Avg 150 ml collected CB = Avg 1.7×10^9 TNC = Avg 8.0×10^6 CD34

IMPORTANT - Collect as much cord blood volume as possible to obtain a critical cell dose for clinical use

Insufficient Volume/Cell count = Fresh HPC Research Use CBU

Inadequate Volume < 100 mL



Inadequate Clinical Volume > 100 mL



Clinical Use Volume > 150 mL



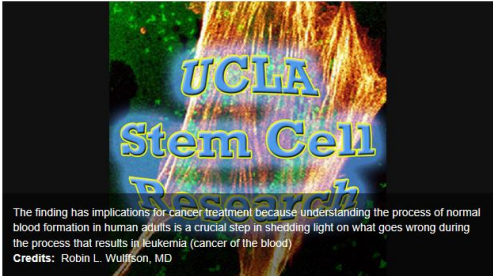
HPC IND Research Use-More than minimal manipulation?

STEM CELL | SEPTEMBER 2, 2012 | BY: ROBIN WULFFSON, M.D.

19 0 5 5

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Get Healthcare alerts! Sign up



The finding has implications for cancer treatment because understanding the process of normal blood formation in human adults is a crucial step in shedding light on what goes wrong during the process that results in leukemia (cancer of the blood).
Credits: Robin L. Wulffson, MD

RELATED TOPICS

- stem cell
- research
- leukemia
- bone marrow
- Missing Link

UCLA researchers have discovered a type of cell that is the "missing link" between bone marrow stem cells and all the cells of the human immune system. They note that their discovery will lead to a greater understanding of how a healthy immune system is produced and how disease can lead to poor immune function. They published their findings on September 2 in the early online edition of the journal Nature Immunology.

The researchers conducted their studies using human bone marrow, which contains all the stem cells that produce blood after birth. "We

The Silk Pincushion Reserve Casino Hotel Miners Pick Bed and Breakfast

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MEDIPost:

CARTISTEM is a drug for the treatment of knee cartilage defects caused by degeneration or repeated trauma in the osteoarthritis. It is composed of mesenchymal stem cells **isolated and expanded from umbilical cord blood**. CARTISTEM does not require donor-recipient matching, nor does it present any immune rejection problem. It is available to any patient and effective even for those above the ages of 50. It is undergoing Phase I/IIa clinical trials

PNEUMOSTEM aims to treat pulmonary disorders such as bronchopulmonary dysplasia (BPD). BPD is a lung disorder affecting prematurely born infants, causing severe degree of inflammation and fibrosis (tissue-scarring) in the lungs. Pre-clinical study using animal models

NEUROSTEM aims to treat patients suffering from neuro-degenerative disorders such as Alzheimer's disease (AD), Amyotrophic Lateral Sclerosis (ALS) and stroke via recovery of functionality and tissues of the central nervous system

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Bedford bear reportedly spotted in Solon

Home > Health and Fitness > Health News

Cleveland researchers find key to stem-cell therapy for MS patients: Discoveries

Published: Tuesday, September 04, 2012, 7:21 AM Updated: Tuesday, September 04, 2012, 2:02 PM

By Brie Zeltner, The Plain Dealer


118 people recommend this. Sign Up to see what your friends recommend.

Comment 1 Tweet 63 Print

CLEVELAND, Ohio -- One of the most promising and exciting treatment avenues for multiple sclerosis is the use of a patient's own stem cells to try to stop -- or even repair -- some of the disease's brain tissue damage.

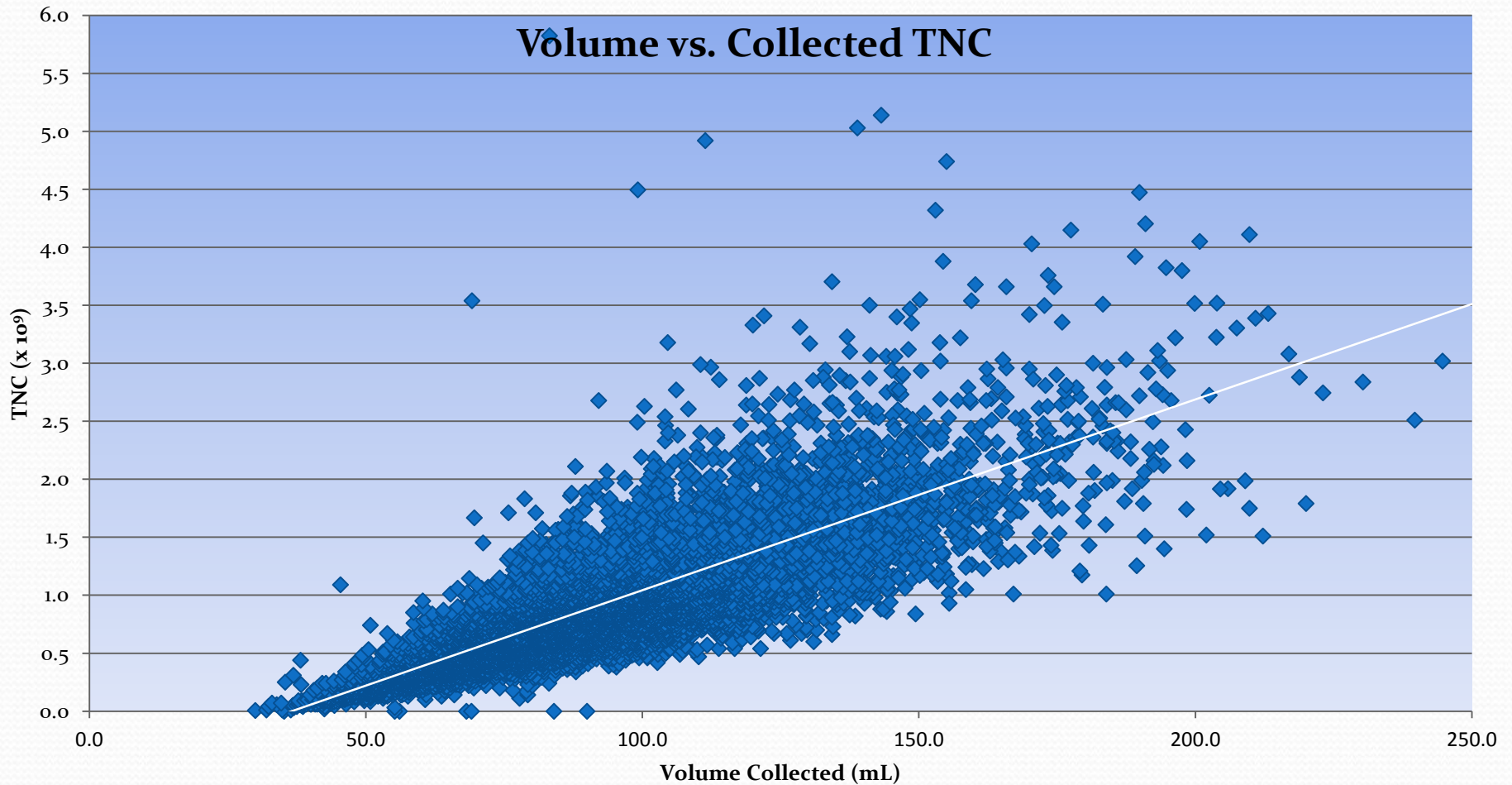
But injecting a patient with a dose of his or her own bone-marrow stem cells was actually a pretty crude method of treating the disease, because no one was quite sure how or why it worked. **Last year**, doctors at the Cleveland Clinic, University Hospitals Seidman Cancer Center and Case Western Reserve University began trying this for MS patients in a Phase 1 clinical trial after positive results were seen in mice.

Multiple sclerosis is an autoimmune disease in which the immune system attacks the myelin sheaths that surround and protect nerve



Case Western Reserve University
Robert Miller, professor in the department of neurosciences at Case Western Reserve University

CB Potency: Collected Volume, Total Nucleated Cell (TNC)



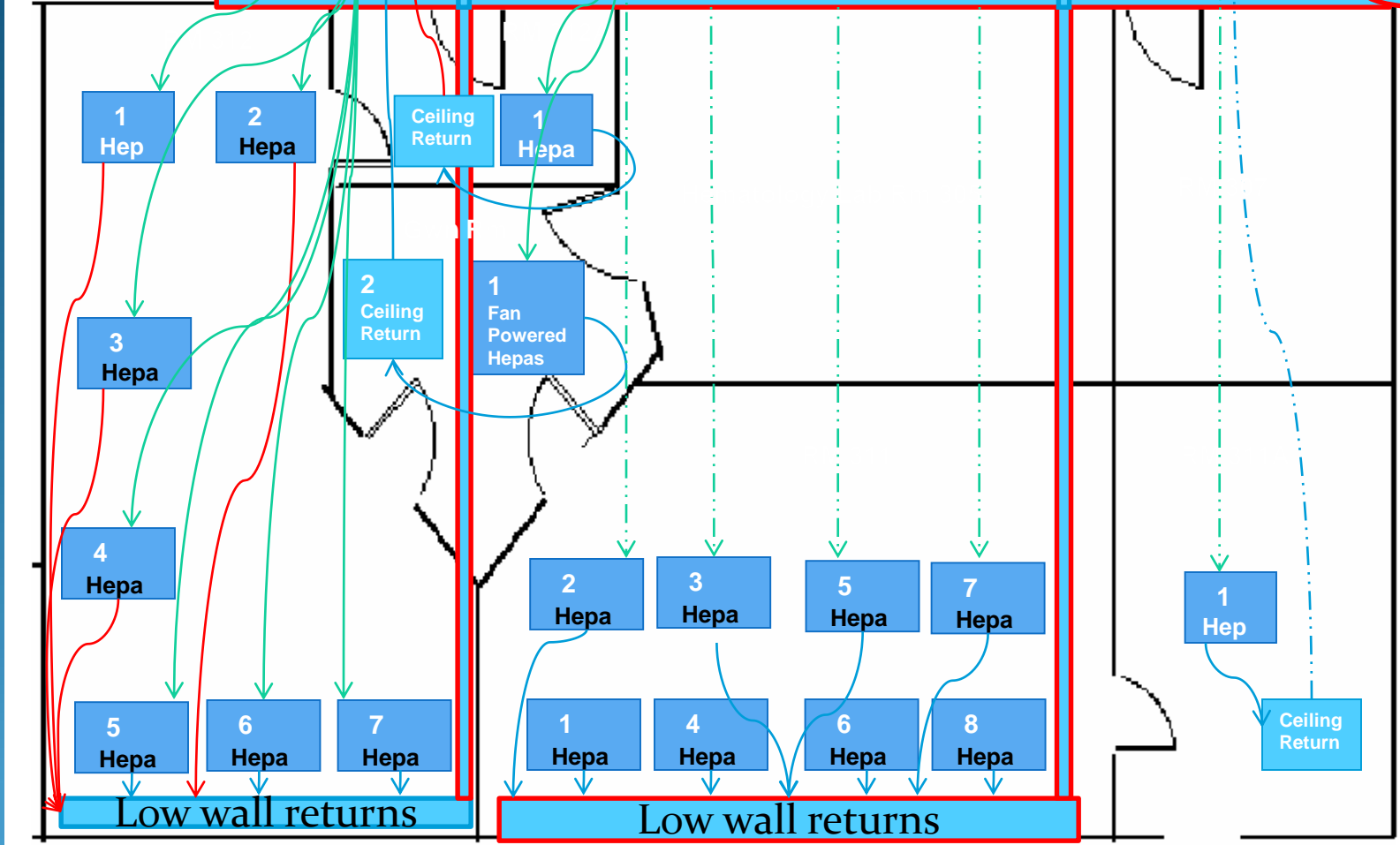
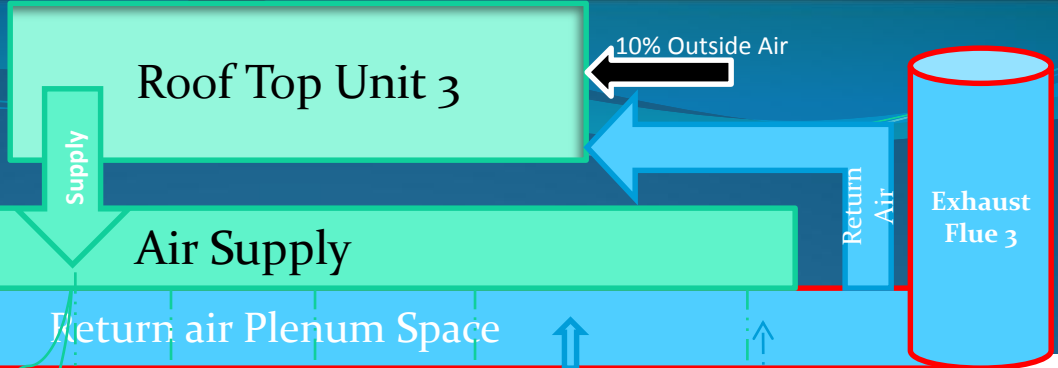
Minimal CB Manipulation Closed Processing System GMP Clean Room Processing Required

Twenty two separate equipment, clean room, and process validations performed and submitted to FDA after August 2015 Facility move.

FDA Prior Approval Supplement (PAS) to obtain approval to process licensed CBU. IND CBU production allowed for clinical use, until PAS approval.



UCCBB Processing and Clean Room
Cleanroom Filter HVAC Layout
ClinImmune Labs
University of Colorado Cord Blood and
Stem Cell Laboratory
BioScience Place
12705 E Montview Blvd
Suite 250
Aurora, CO 80045



UCCBB Package Insert for Cord Blood Injection

Licensed products require a package insert from the manufacturer which lists all components of the product, dose instructions and possible adverse events associated with infusion.

These highlights do not include all the information needed to use HPC, Cord Blood safely and effectively. See full prescribing information for HPC, Cord Blood.

HPC, Cord Blood
Injectable Suspension for Intravenous Use
Initial U.S. Approval: 2012

WARNING: FATAL INFUSION REACTIONS, GRAFT VERSUS HOST DISEASE, ENGRAFTMENT SYNDROME, AND GRAFT FAILURE

See full prescribing information for complete boxed warning.

- **Fatal infusion reactions:** Monitor patients during infusion and discontinue for severe reactions. Use is contraindicated in patients with known allergy to dimethyl sulfoxide (DMSO), Dextran 40 or human serum albumin. (4, 5.1, 5.2)
- **Graft-vs-host disease (GVHD):** GVHD may be fatal. Administration of immunosuppressive therapy may decrease the risk of GVHD. (5.3)
- **Engraftment syndrome:** Engraftment syndrome may be fatal. Treat engraftment syndrome promptly with corticosteroids. (5.4)
- **Graft failure:** Graft failure may be fatal. Monitor patients for laboratory evidence of hematopoietic recovery. (5.5)

INDICATIONS AND USAGE

HPC (hematopoietic progenitor cells), Cord Blood is an allogeneic cord blood hematopoietic progenitor cell therapy indicated for use in unrelated donor hematopoietic progenitor cell transplantation procedures in conjunction with an appropriate preparative regimen for hematopoietic and immunologic reconstitution in patients with disorders affecting the hematopoietic system that are inherited, acquired, or result from myeloablative treatment. (1)

The risk/benefit assessment for an individual patient depends on the patient characteristics, including disease, stage, risk factors, and specific manifestations of the disease, on characteristics of the graft, and on other available treatments or types of hematopoietic progenitor cells. (1)

DOSAGE AND ADMINISTRATION

- Unit selection and administration of HPC, Cord Blood should be done under the direction of a physician experienced in hematopoietic progenitor cell transplantation.

FULL PRESCRIBING INFORMATION: CONTENTS*

WARNING: FATAL INFUSION REACTIONS, GRAFT VERSUS HOST DISEASE, ENGRAFTMENT SYNDROME, AND GRAFT FAILURE

- INDICATIONS AND USAGE
- DOSAGE AND ADMINISTRATION
 - Dosing
 - Preparation for Infusion
 - Administration
- DOSAGE FORMS AND STRENGTHS
- CONTRAINDICATIONS
- WARNINGS AND PRECAUTIONS
 - Allergic Reactions and Anaphylaxis
 - Infusion Reactions
 - Graft-versus-Host Disease
 - Engraftment Syndrome
 - Graft Failure

cryopreservation. (2.1)

- Do not administer HPC, Cord Blood through the same tubing with other products except for normal saline. (2.3)

DOSAGE FORMS AND STRENGTHS

Each unit contains a minimum of 5×10^6 total nucleated cells with at least 1.25×10^6 viable CD34+ cells at the time of cryopreservation. The exact cryopreservation nucleated cell content of each unit is provided on the container label and accompanying records. (3)

CONTRAINDICATIONS

Known sensitivity to dimethyl sulfoxide (DMSO), Dextran 40 or plasma proteins. (4)

WARNINGS AND PRECAUTIONS

- Allergic Reactions and Anaphylaxis (5.1)
- Infusion Reactions (5.2)
- Graft-versus-Host Disease (5.3)
- Engraftment Syndrome (5.4)
- Graft Failure (5.5)
- Malignancies of Donor Origin (5.6)
- Transmission of Serious Infections (5.7)
- Transmission of Rare Genetic Diseases (5.8)

ADVERSE REACTIONS

Mortality, from all causes, at 100 days post-transplant was 25%. (6.1)

The most common infusion-related adverse reactions ($\geq 5\%$) are hypertension, vomiting, nausea, bradycardia, and fever. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact ClinImmune Labs, University of Colorado Cord Blood Bank (UCCBB) at 303-724-1306 and FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Based on animal data, may cause fetal harm. Use only if clearly needed. (8.1)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 05/2012

8 USE IN SPECIFIC POPULATIONS

- Pregnancy
 - Pediatric Use
 - Geriatric Use
 - Renal Disease
- ## 10 OVERDOSAGE
- Human Overdosage Experience
 - Management of Overdose

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

- Mechanism of Action

14 CLINICAL STUDIES

16 HOW SUPPLIED/STORAGE AND HANDLING

17 PATIENT COUNSELING INFORMATION

Patient Populations infused with UCCBB Cord Blood?

To date:

**There have been a total of 784 UCCBB
CBU shipped for infusion.**

**31 of those shipped were collected in our
partner state of Arizona.**

Average TNC of AZCBU Shipped: 2.4×10^9

1999-2012 UCCBB Recipient Demographics

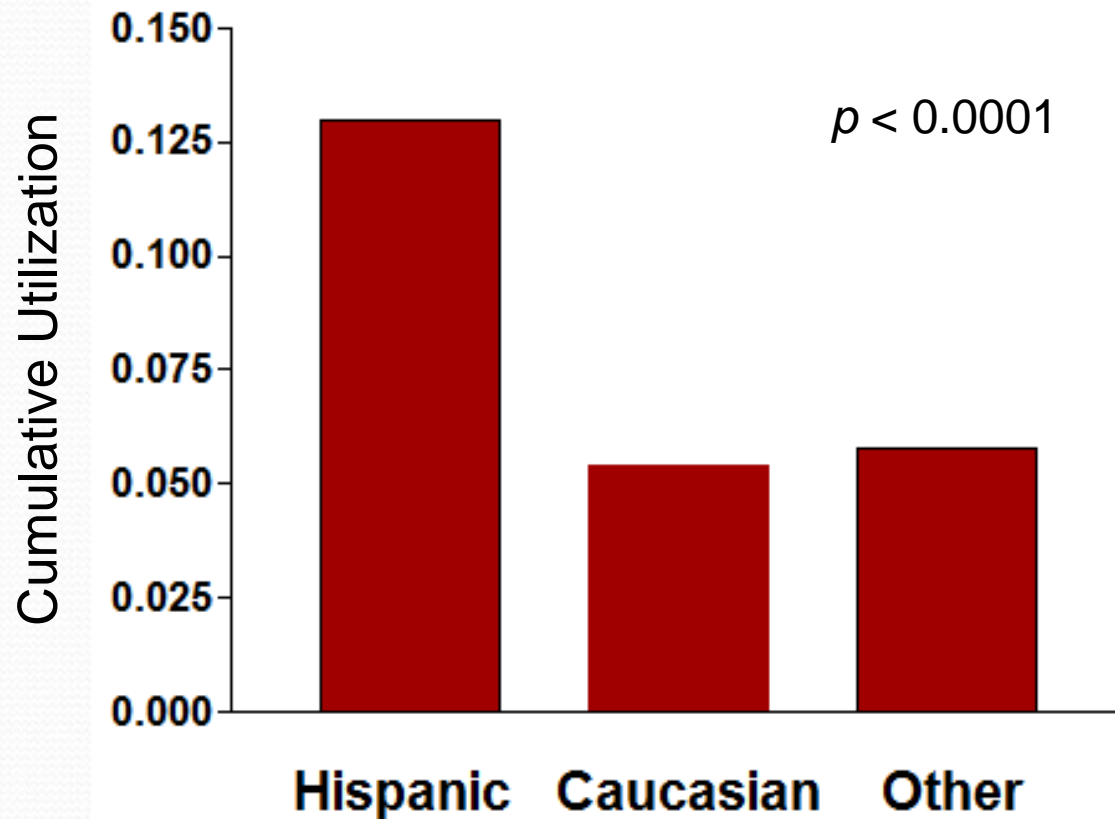
- Review recipient Age, Gender and Diagnosis

	Number of Male	Number of Female	Unknown
Recipient Sex	310 / 539 (58%)	229 / 539 (42%)	4

Recipient Age (yrs) at Infusion	Number of UCCBB Recipients
0-1 yr	72
2-5 yr	91
6-11 yr	91
12-17 yr	57
18-55 yr	152
>55 yr	39

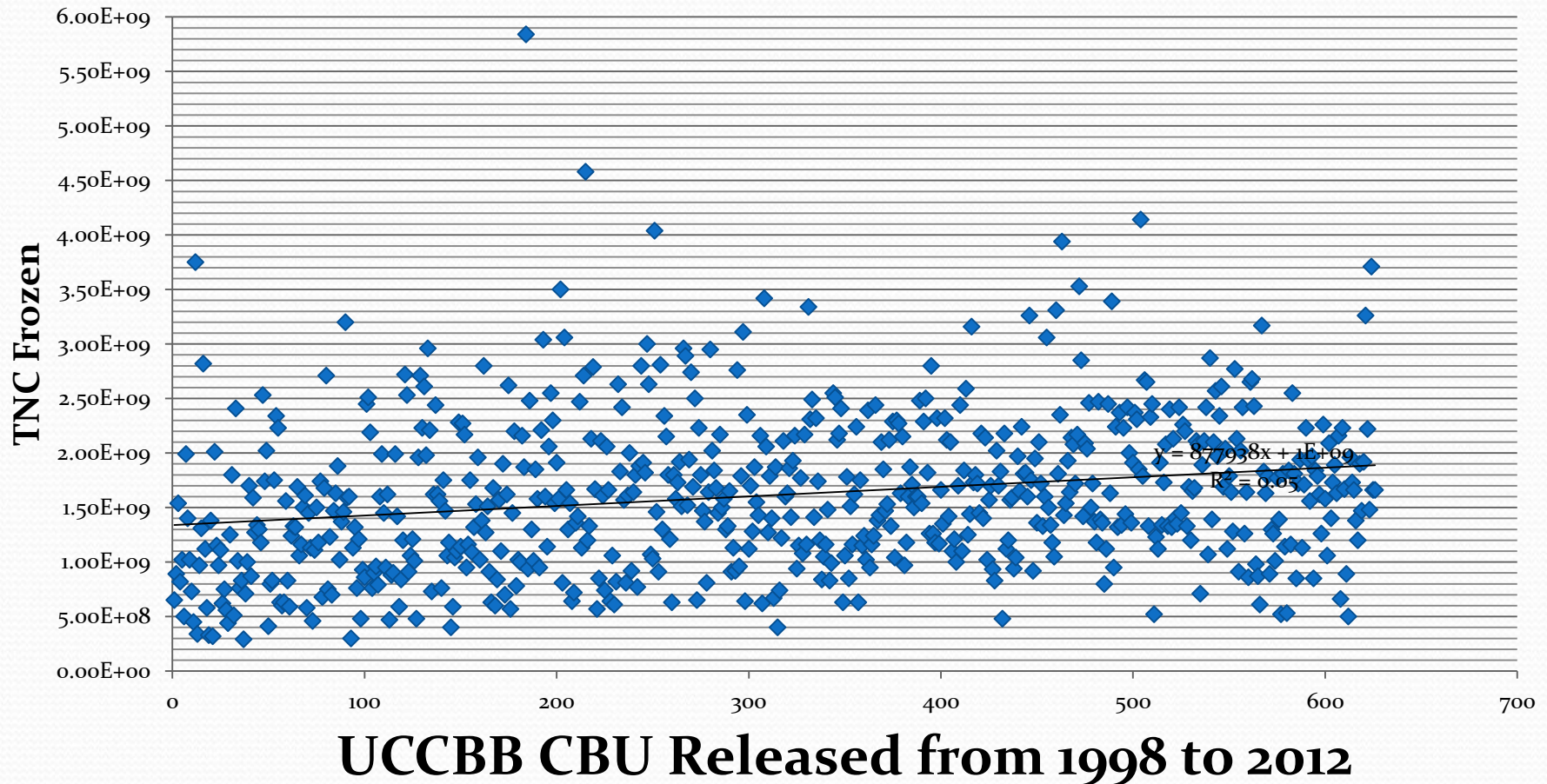
Utilization of UCCBB Minority Cord Blood Units

n = 640



In 2007, CBU required 1.2×10^9 TNC to process, in 2012 that number was increased to Collected 2.0×10^9 (1.8 banked) to focus on banking units that can be used clinically.

CBU Released Over Time and TNC



First TCH HPC, Cord Blood Transplant

Birth: January 17, 1996

Diagnosis of very high risk Acute Lymphoblastic Leukemia (ALL), t(4;11), April 1996

HSCT: July 24, 1996



1 year after HSCT



4 years after HSCT

There are over 310 patients alive today because of the You!

**14 yo boy (DOB 5/85) Diagnosis: Acute
Myelogenous Leukemia (AML) March 1997
Relapse**

Proposed rx: Allogeneic BMT

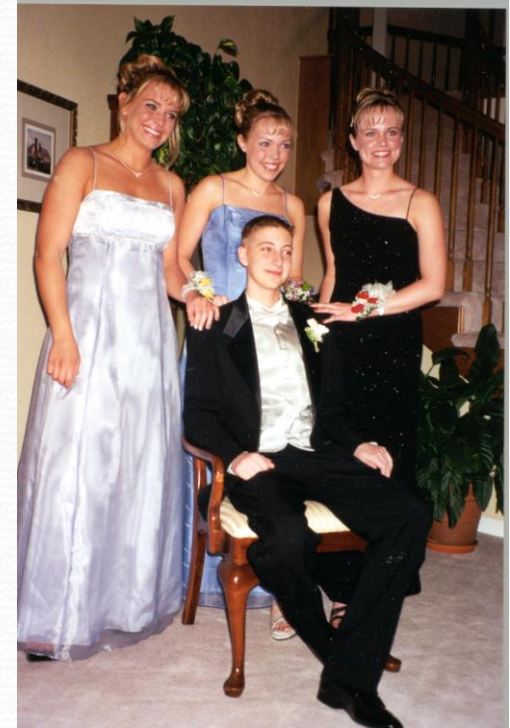
No Matched sibling or other relatives

Matched unrelated marrow: Available in 3-4 months

Matched unrelated cord blood: 5/6 match available immediately

**Unrelated cord blood HSCT
June 1999**

**Outcome: Complete Remission
In College**



R. Quinones

Thank You to Our Public Bank Collection teams in Arizona!

Learning Objectives:

CBB History and Use-including Research: AZ CBU are banked as licensed drugs regulated by the FDA. Donors have the option to opt out of “Research Use” of CBU. Hospital IRB are given the option of oversight for CB banked clinically and others as de-identified waste products used for research.

Challenges and Improvement options: AZ CBU were being banked with collected TNC $\geq 1.5 \times 10^9$. This results in a banked/frozen TNC of about 80% recovery ($\geq 1.2 \times 10^9$) that is too small to be considered clinically useful.

Raising the collected TNC to 2.0×10^9 will and education on volume and sterility tips for quality CBU banking is helpful.

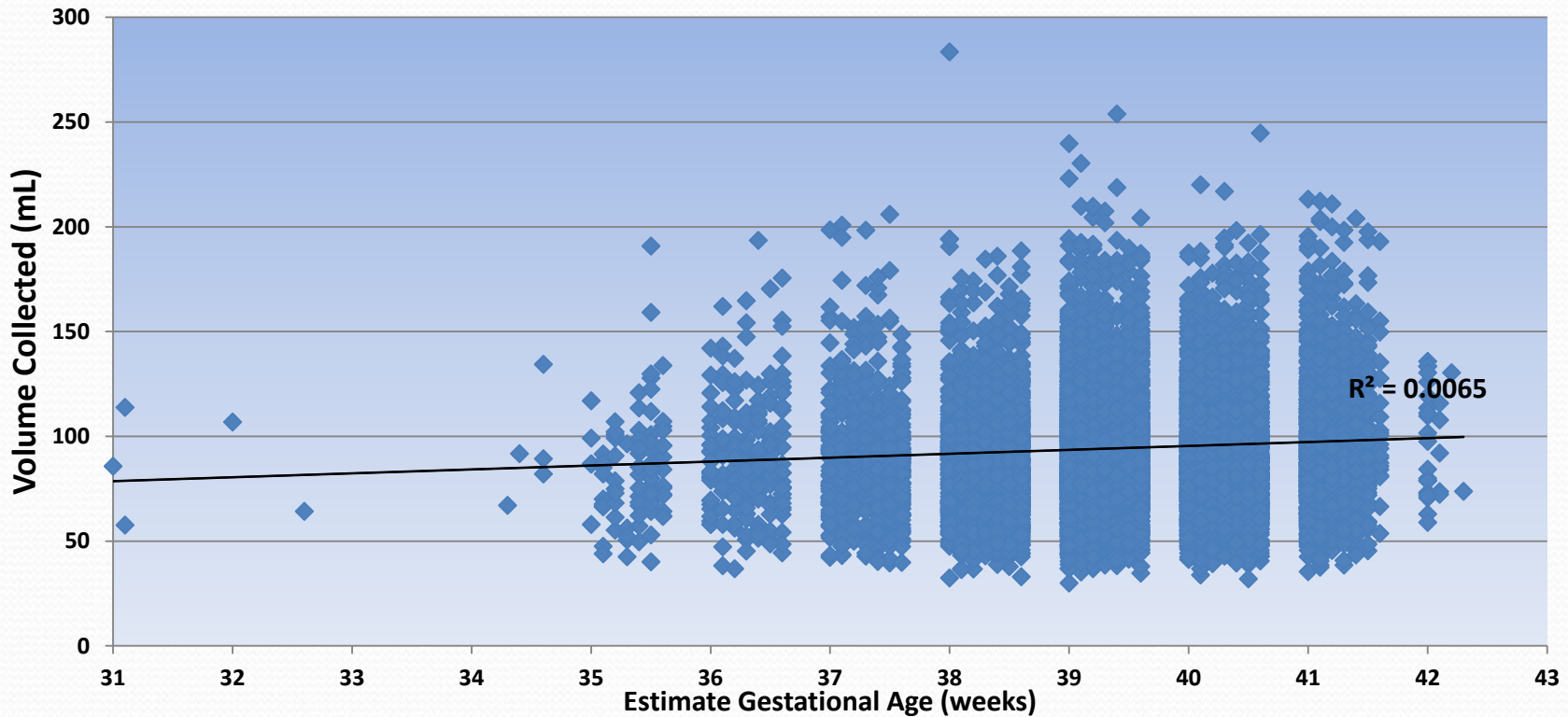
Reach Diverse Populations: AZ CBU banked are primarily Hispanic and most of the units released for transplant are of Hispanic race, thus serving a diverse population of recipients.

Clinical Applications: AZ fresh collected CBU that are not banked for clinical use and are not “Opted out” for research by the donor, are released to researchers in AZ. Clinical research is regulated by the FDA and may be utilized under the NMDP IND if minimally manipulated and not qualified as licensed CBU. UCCBB CBU transplants have saved the lives of many recipients with over 20 different diagnosis.

FDA Licensed Banking Costs per Unit
(1,500 units per year @ 25% of collections)

• Collections	\$ 694	
• Processing	\$ 412	
• Post processing	\$ 415	
• Testing	\$ 432	
• Space, equipment, maintenance		\$ 490
• Regulatory and informatics	\$ 202	
• Indirect costs	\$ 185	
Total	\$2,829	
HRSA funding	\$1,282	
Net	-\$1,547	

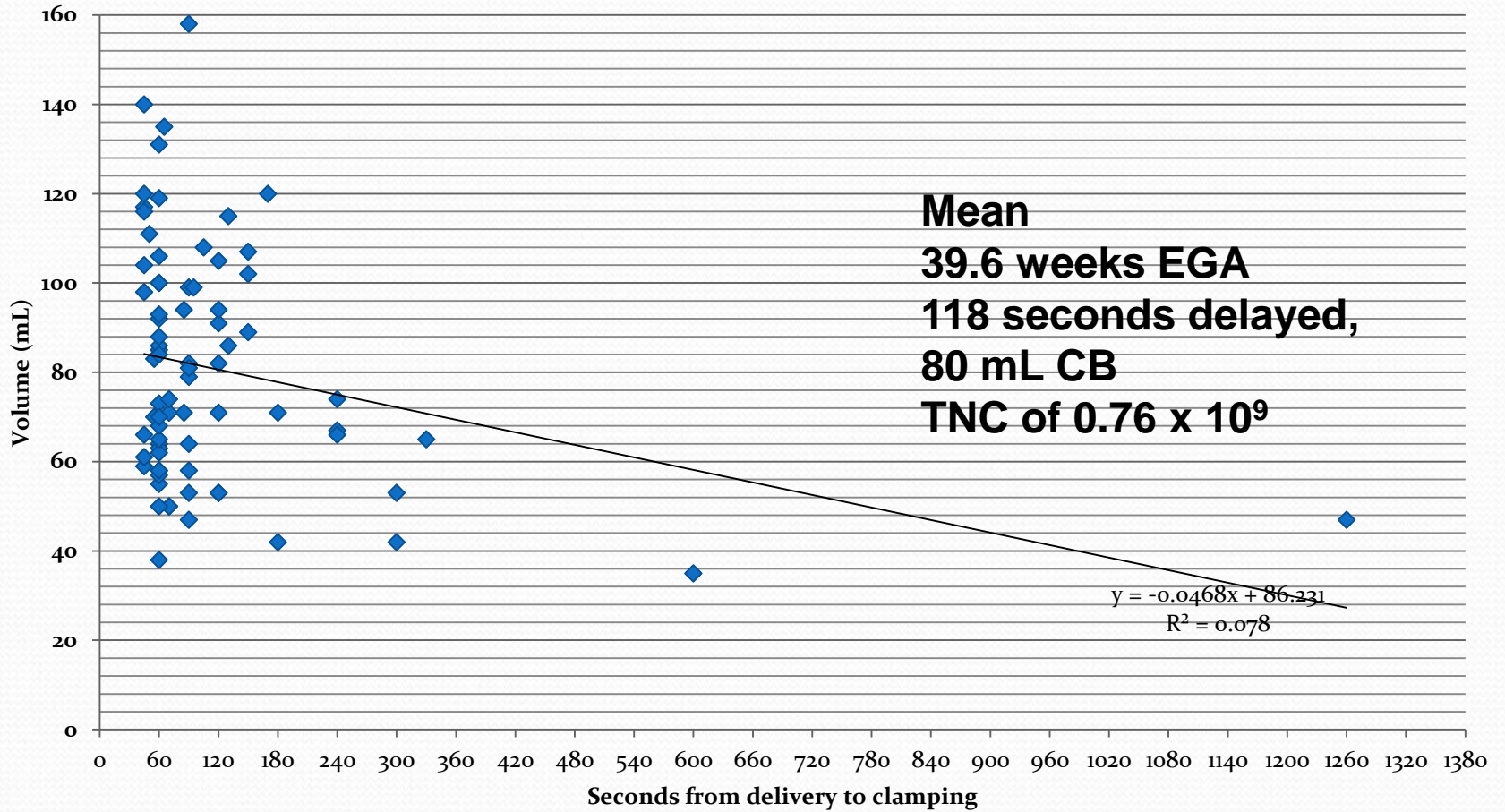
EGA vs. Collection Volume



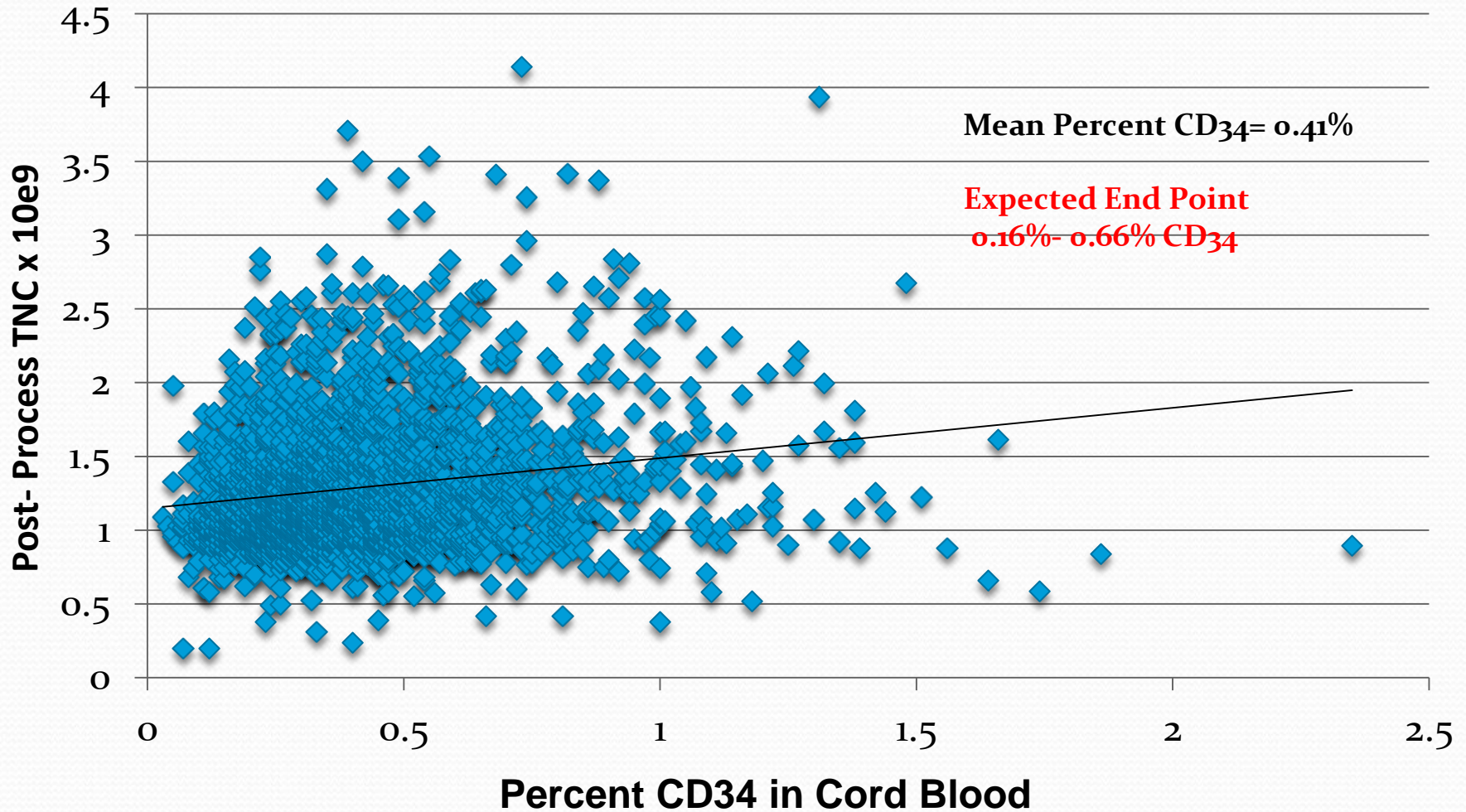
Correlation between EGA and volume collected (total cords)

- Avg. Vol./TNC Col. EGA 35=84.0 mL/0.593
- Avg. Vol./TNC Col. EGA 36=90.8 mL/0.715
- Avg. Vol./TNC Col. EGA 37=90.2 mL/0.756
- Avg. Vol./TNC Col. EGA 38=89.9 mL/0.830
- **Avg. Vol./TNC Col. EGA 39=95.5 mL/0.950**
- Avg. Vol./TNC Col. EGA 40=94.9 mL/1.019
- Avg. Vol./TNC Col. EGA 41=98.4 mL/1.089
- Avg. Vol./TNC Col. EGA 42=96.8 mL/1.049

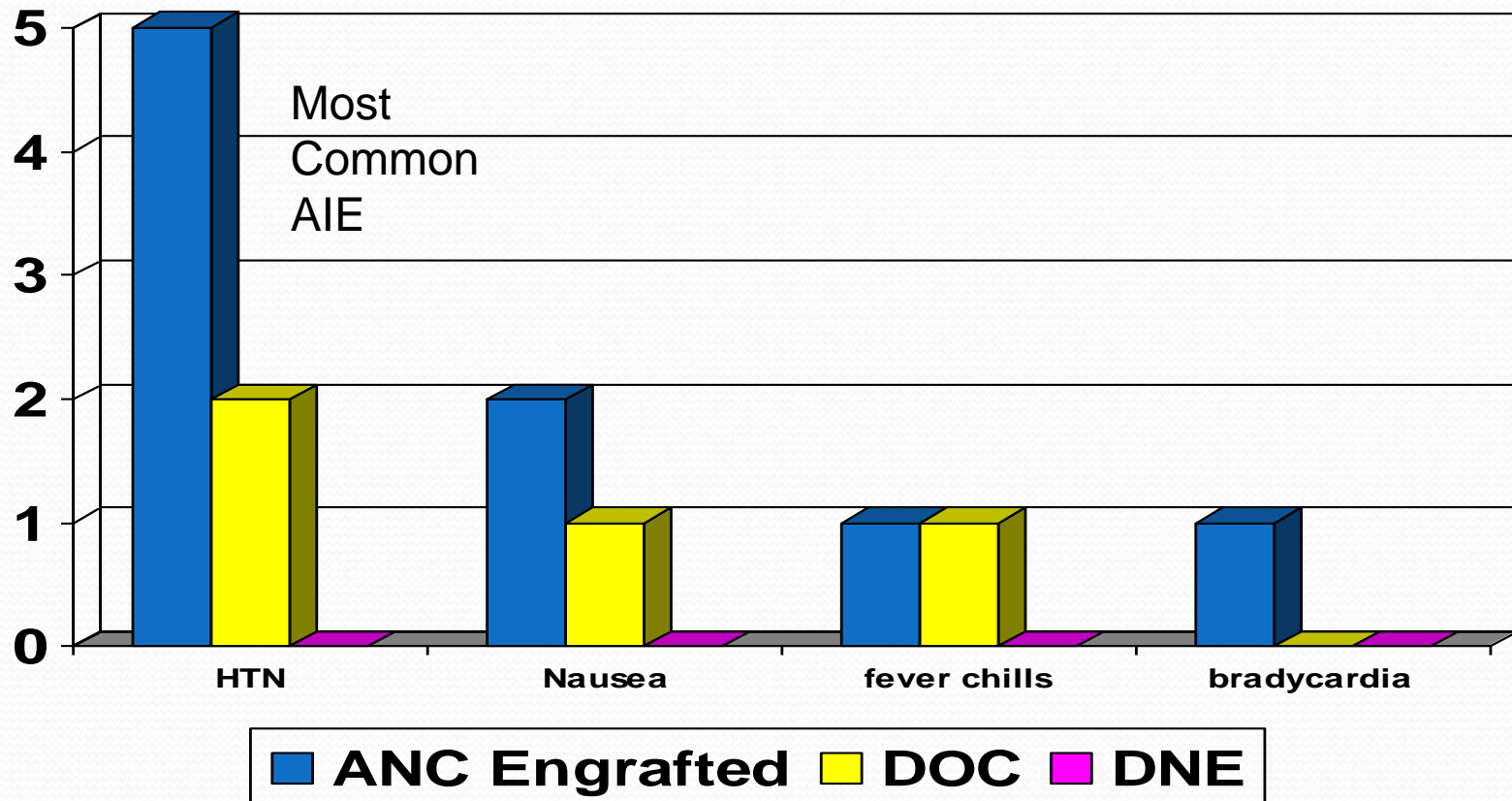
Delayed Cord Clamping Review N=78



Percent of TNC that are Stem Cells (CD 34)



21 CFR 211.198-Subpart J 1271.320-Subopart D 127.350-subpart E
Complaint Files and Reports of Adverse Infusion Experiences





Access to Transplant

Karen Dodson

Chief Operations Officer

Overview

- Need for Transplant
- Potential Barriers to Transplant and Solutions
- Economic Pressures and Solutions for Cord Blood Banks

The Reason Be The Match Exists

- Our Mission

We save lives through cellular therapy

- Our Moonshot

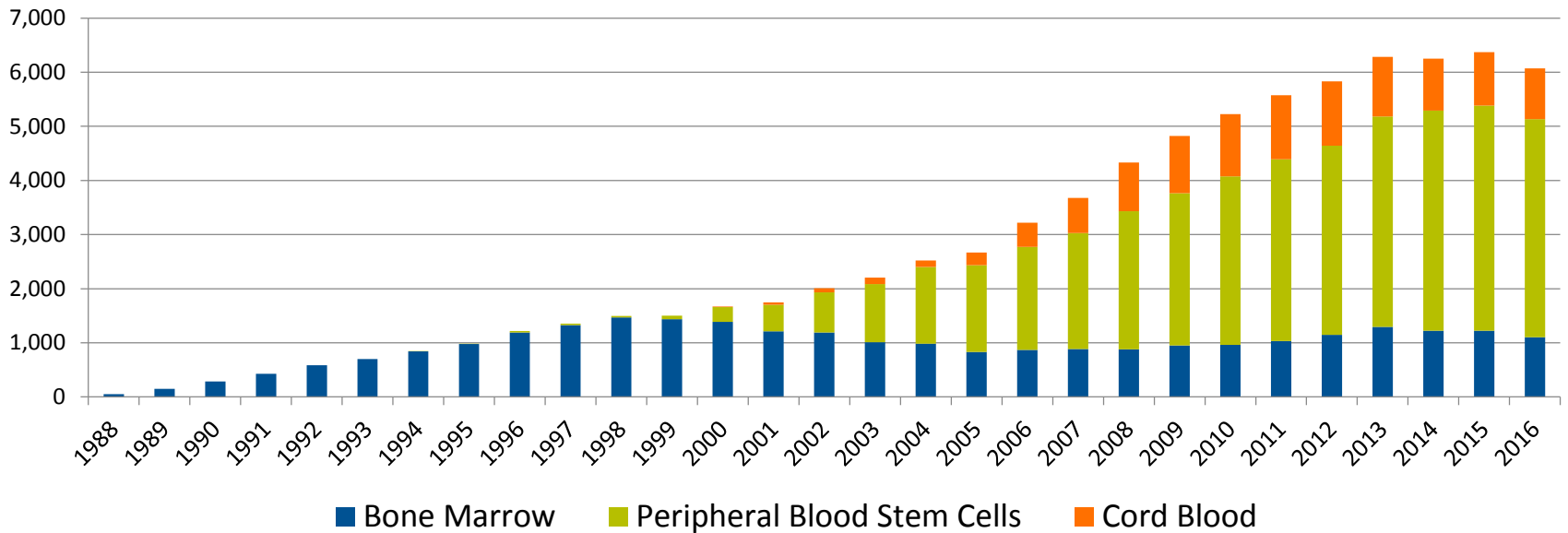
Serve all who need cellular therapy

- The Need

20,700 related and unrelated transplants per year

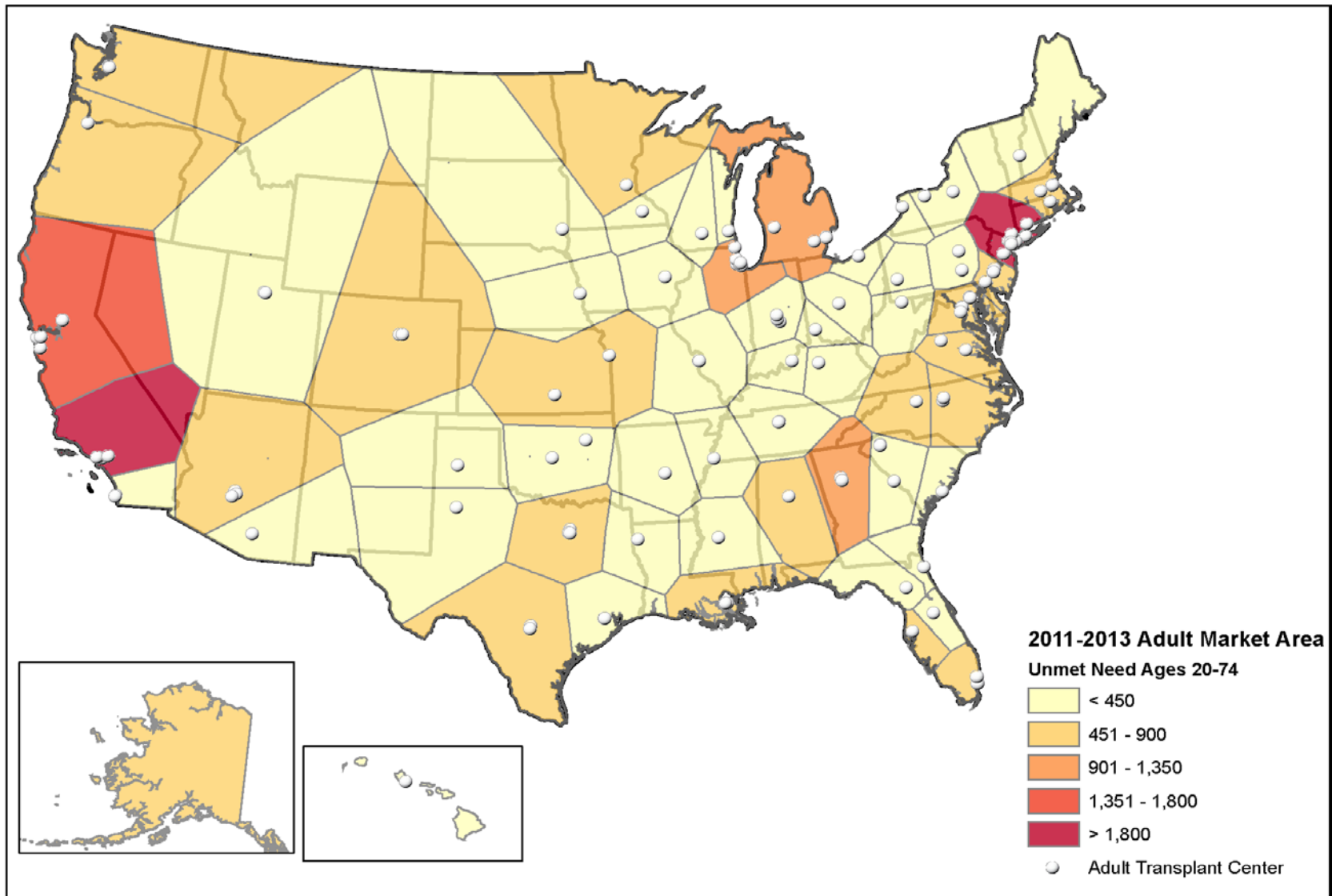
- 4,600/year for ages 0-19
- 16,100/year for ages 20-74

Transplants Facilitated by Be the Match

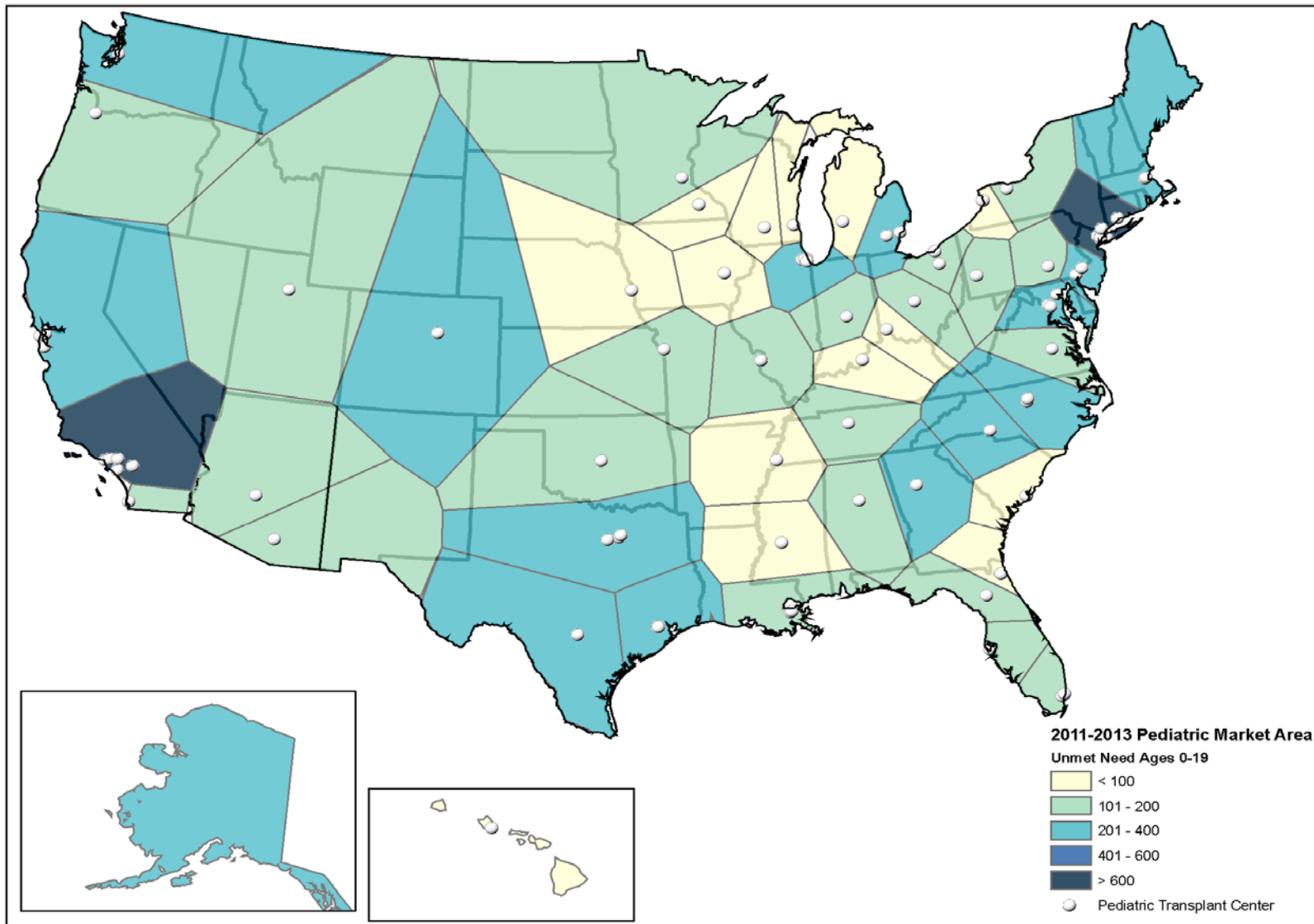


FY 2016 is Forecast

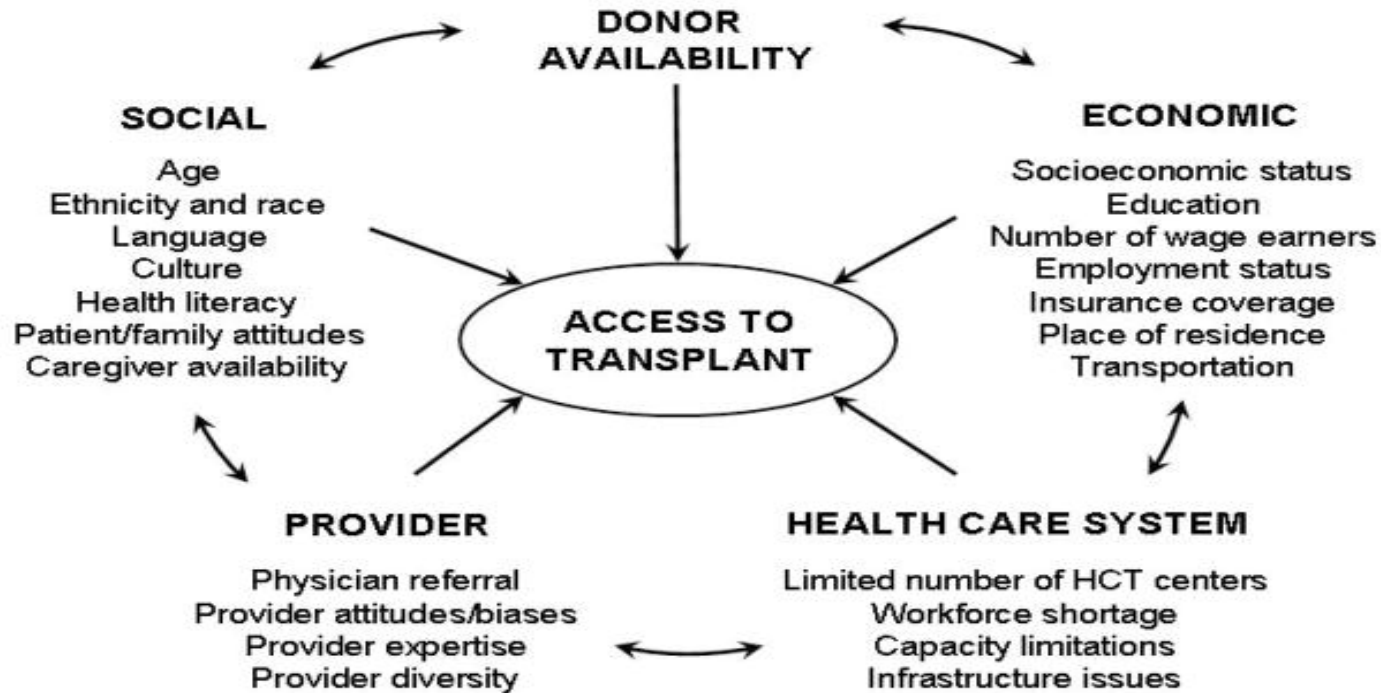
Unmet Need U.S. Market Areas (2011-2013) - Adult Ages 20-75 All Indications



Unmet Need U.S. Market Areas (2011-2013) - Pediatrics Ages 0-19



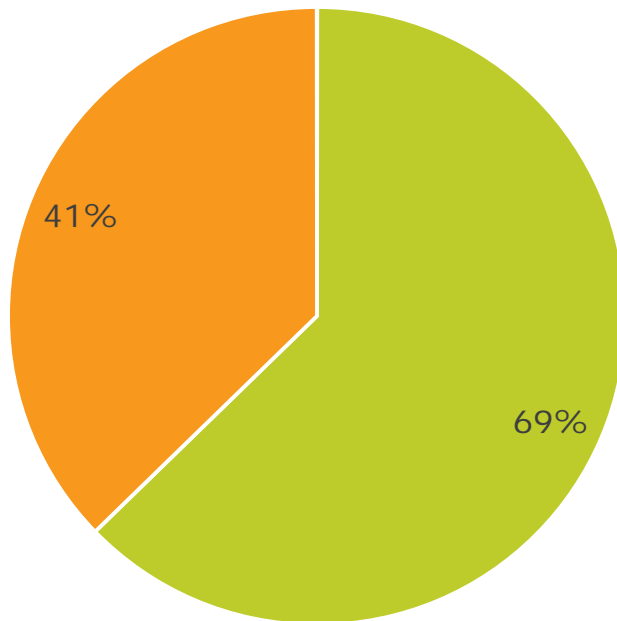
Potential Barriers to Unrelated Transplant



Source: Majhail NS, Omondi NA, Denzen E, Murphy EA, Rizzo JD. Access to Hematopoietic-cell Transplantation in the United States. *Biol Blood Marrow Transplant.* 2010;16(8):1070-1075

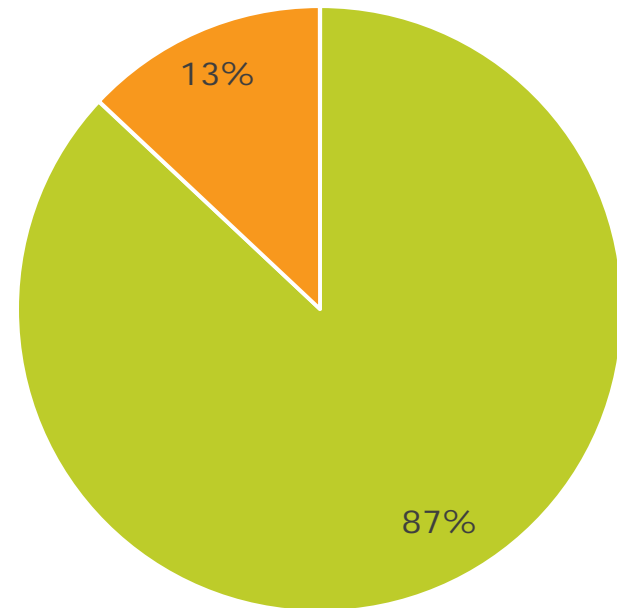
Availability: Cord Blood Increases Access for People of Color

CBU



■ Caucasian ■ People of Color

Adult Donor



■ Caucasian ■ People of Color

Economic: More People Have Insurance

Percentage Uninsured in the U.S., by Quarter

Do you have health insurance coverage?

Among adults aged 18 and older

■ % Uninsured

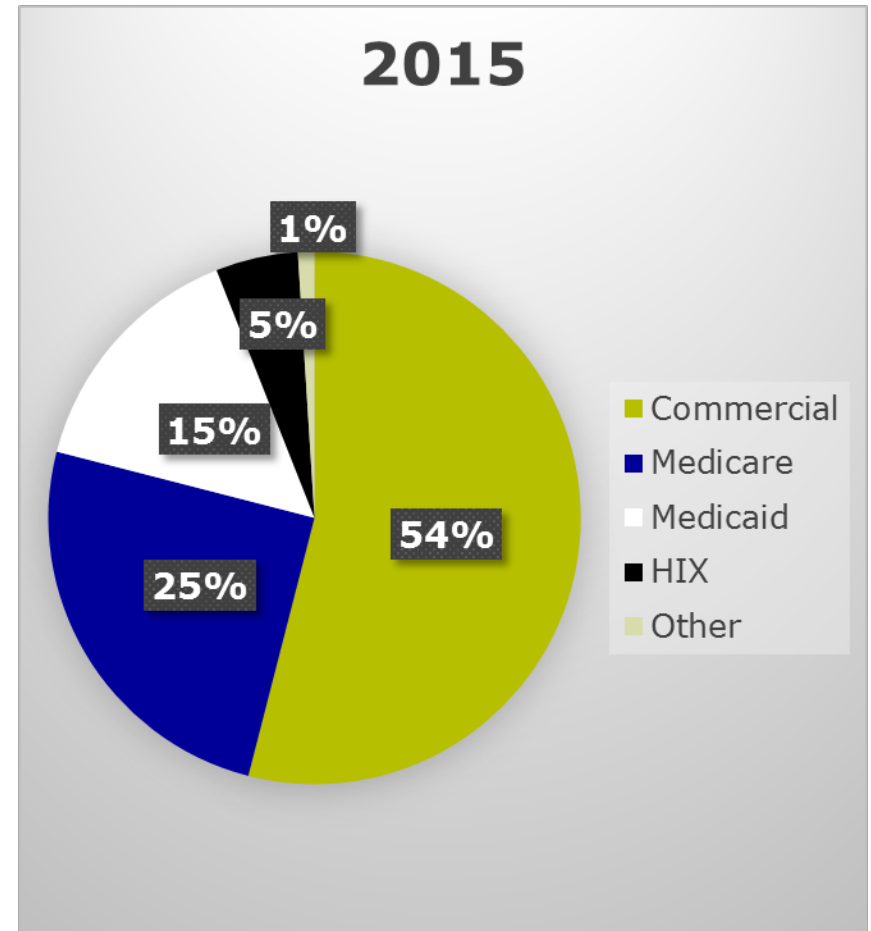
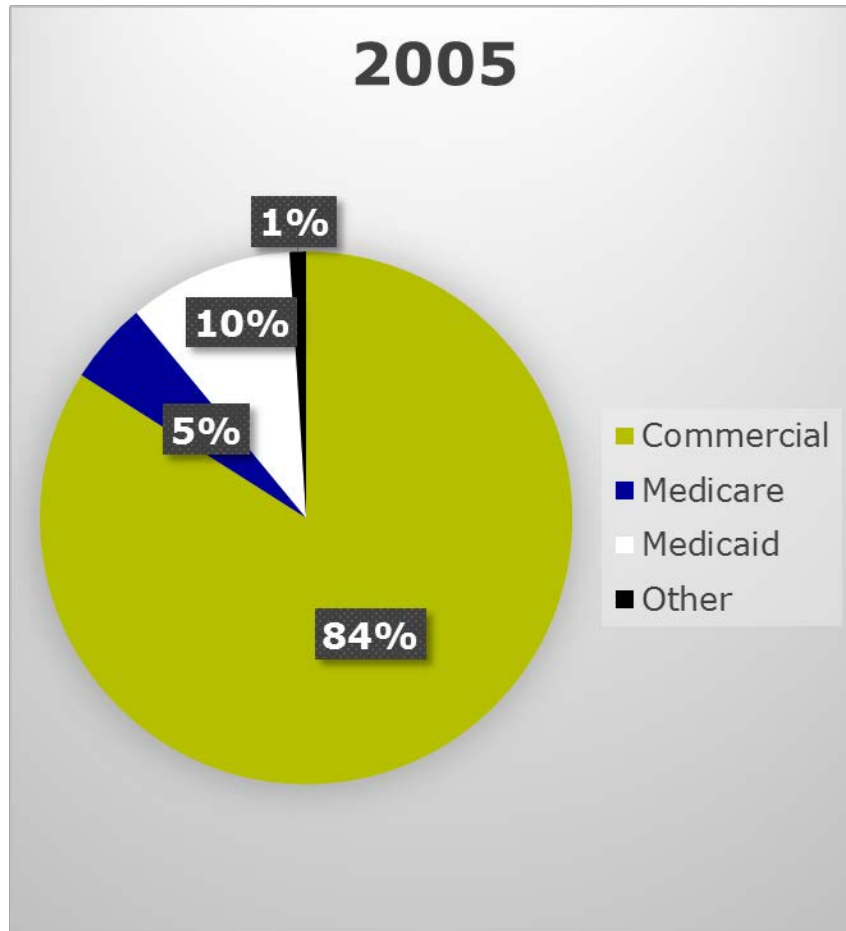


Quarter 1 2008-Quarter 1 2015

Gallup-Healthways Well-Being Index

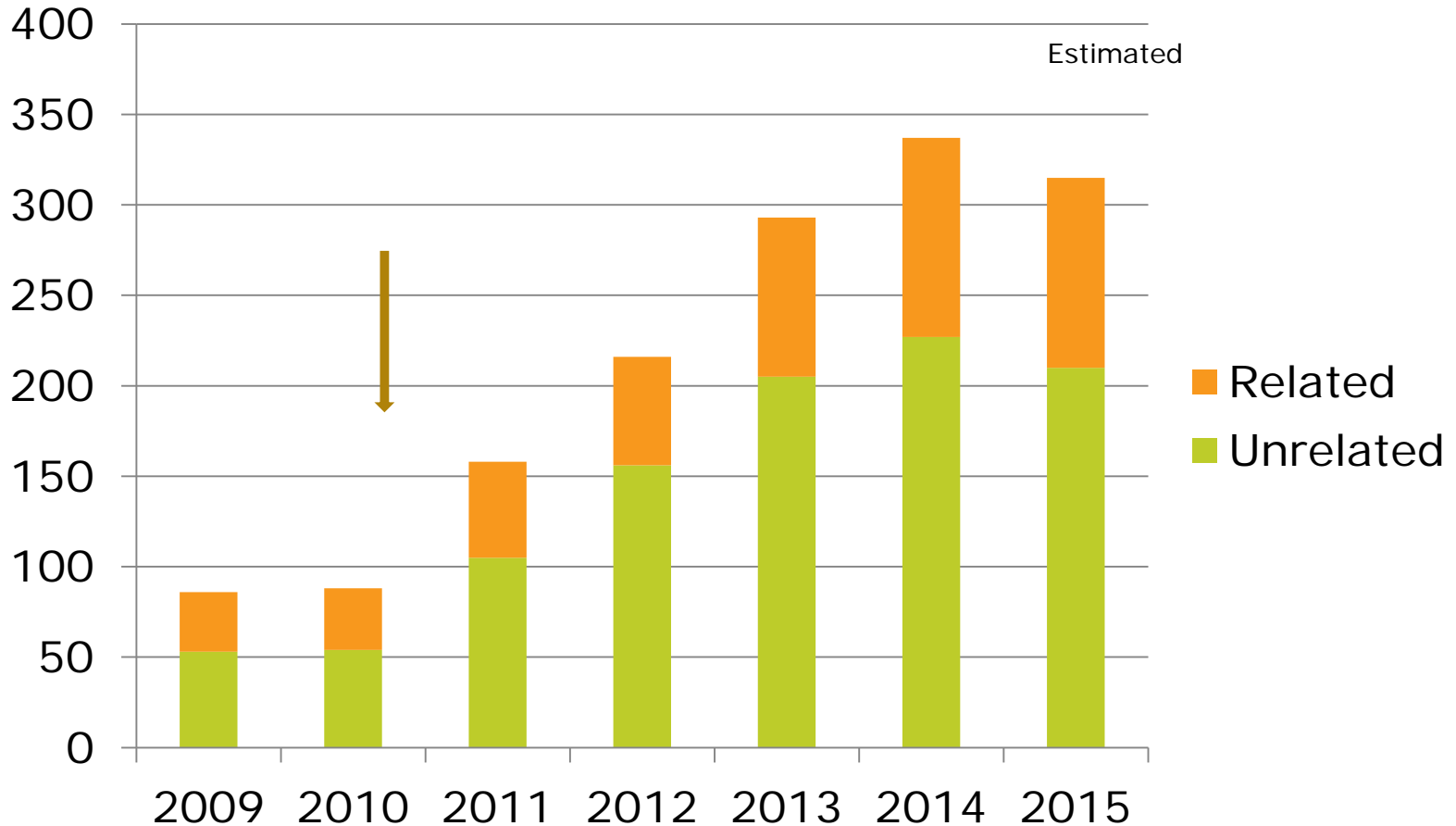
GALLUP®

Economic: Changes in Payer Mix



Economic: What happens when a barrier is removed?

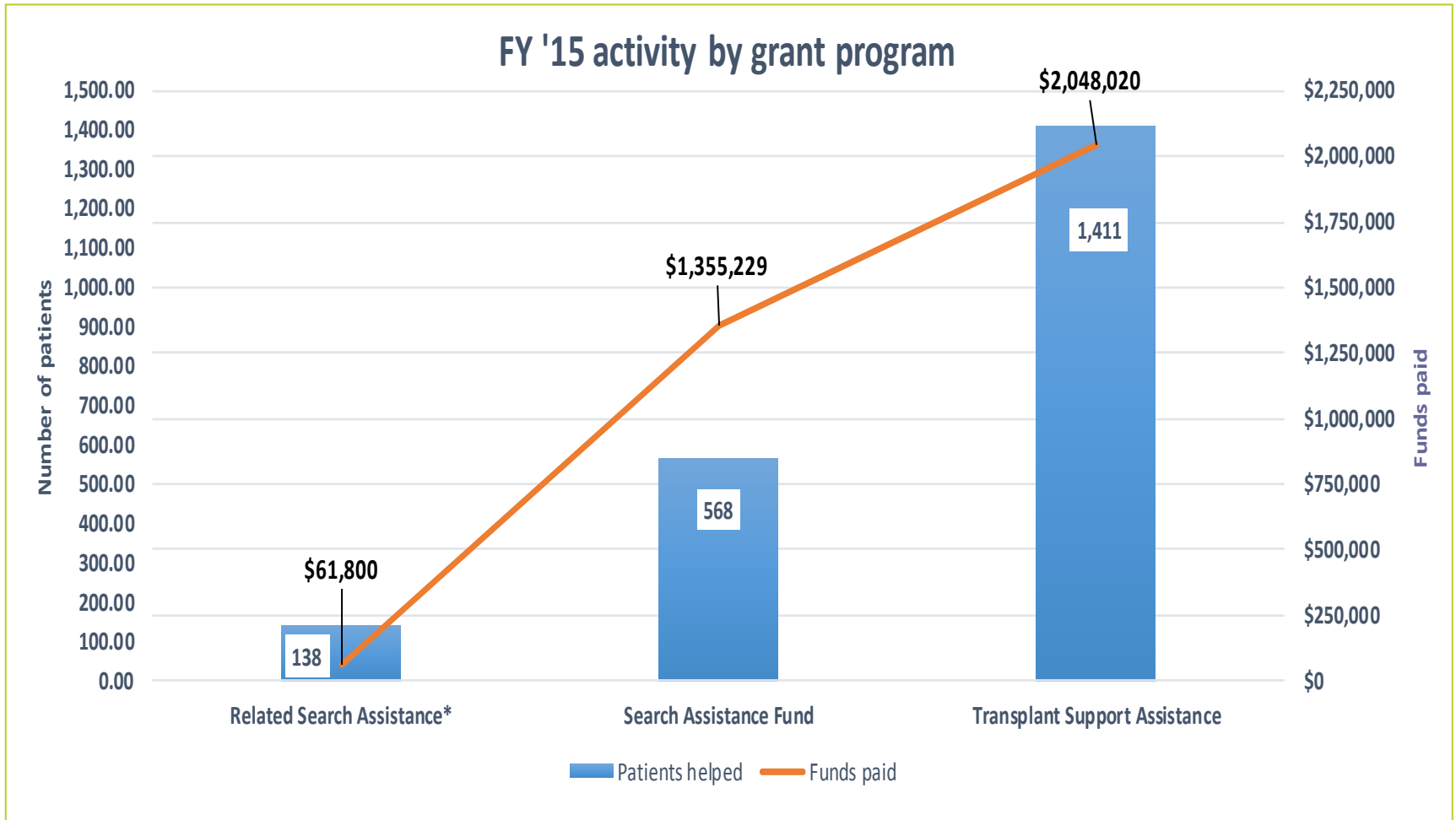
HCT in US for MDS over age 65 and CMS coverage



CMS Decision 2016: New Indications for Coverage

- Prospective Study for Sickle Cell Disease, Multiple Myeloma and Myelofibrosis
- **Principal Objective:** test whether allogeneic HCT improves health outcomes of affected beneficiaries (no pathogenesis or toxicity studies)
 - Compare **survival** with non-allogeneic HCT therapy
 - Adequately control for **selection bias** and potential confounding by **specific prognostic factors**
 - Address **GVHD** and **transplant-related adverse events**

Patient Assistance Program



Health Care System: Transplant Center Capacity

- Workforce
 - Education for emerging providers
 - Research focused on the multidisciplinary team
- Space
 - Transplant unit and clinic capacity
 - Patient housing challenges and potential interventions
- Funding
 - Market maps and market potential

Providers:

Late or Missing Referrals for TX

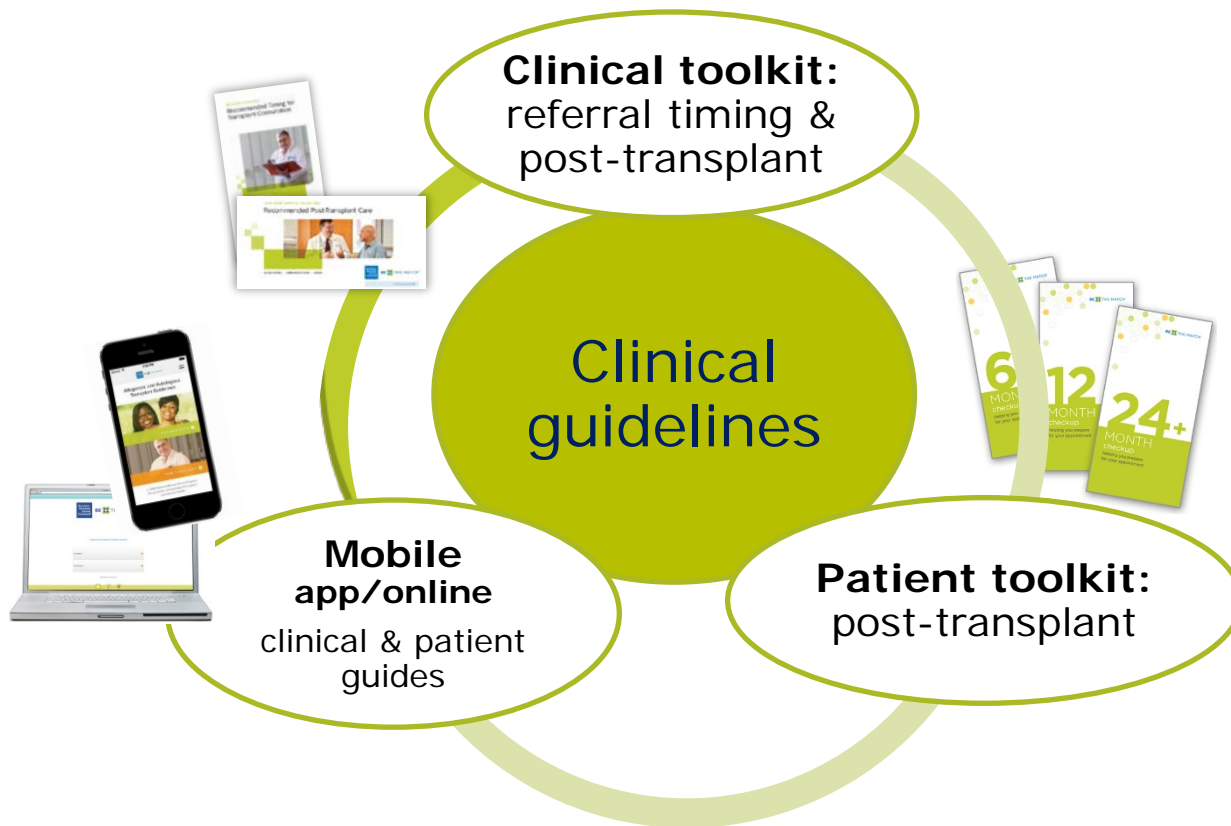
Referring physicians may:

- Believe that transplant outcomes have not improved
- Lack understanding of which patients to refer and timing
- Worry about managing post-transplant care

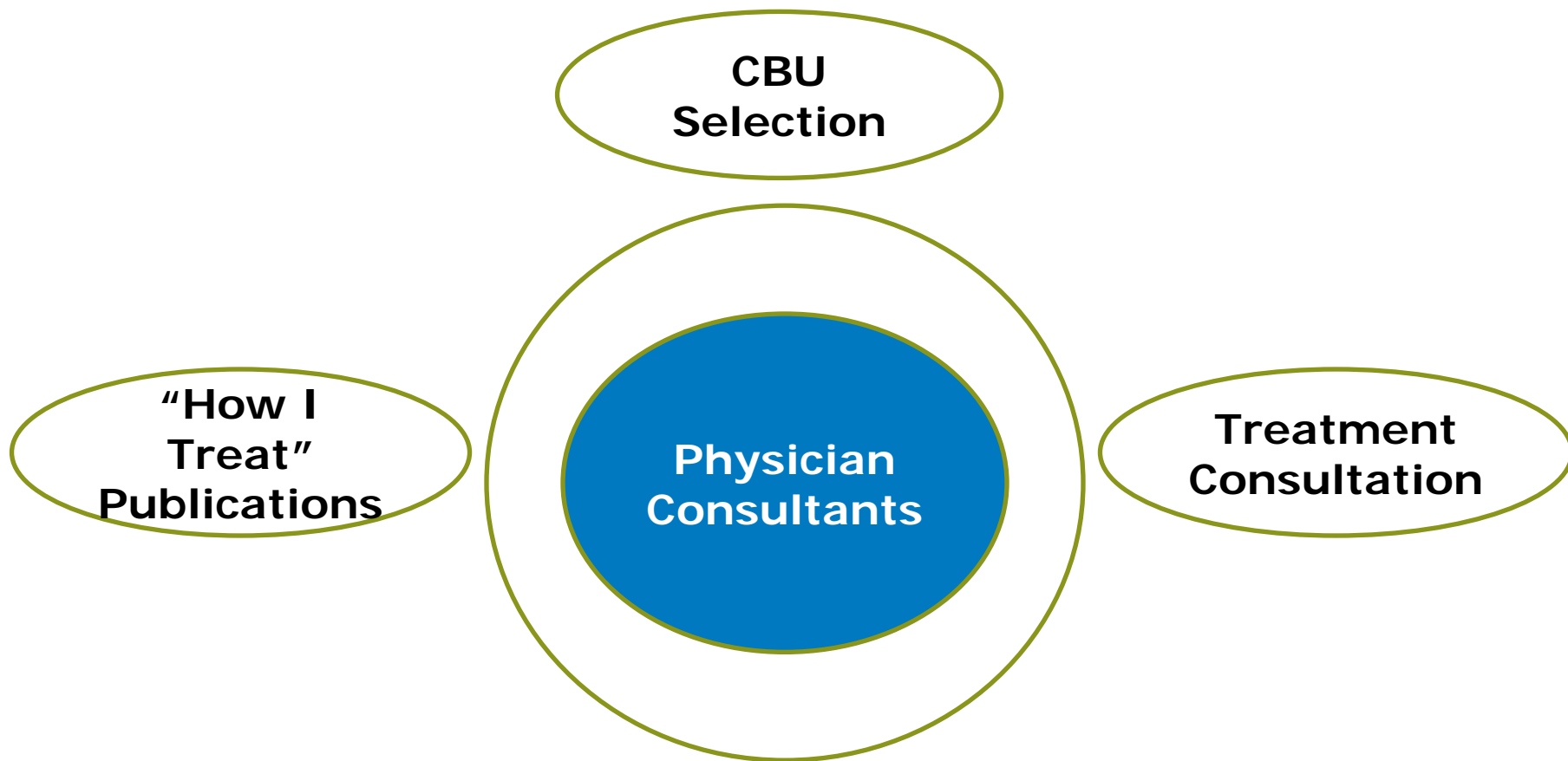
Transplant physicians may:

- Desire further access to expertise about cord blood unit selection and transplant

Providers: Increasing Patient Referrals



Providers: Leveraging Cord Blood Transplant Expertise



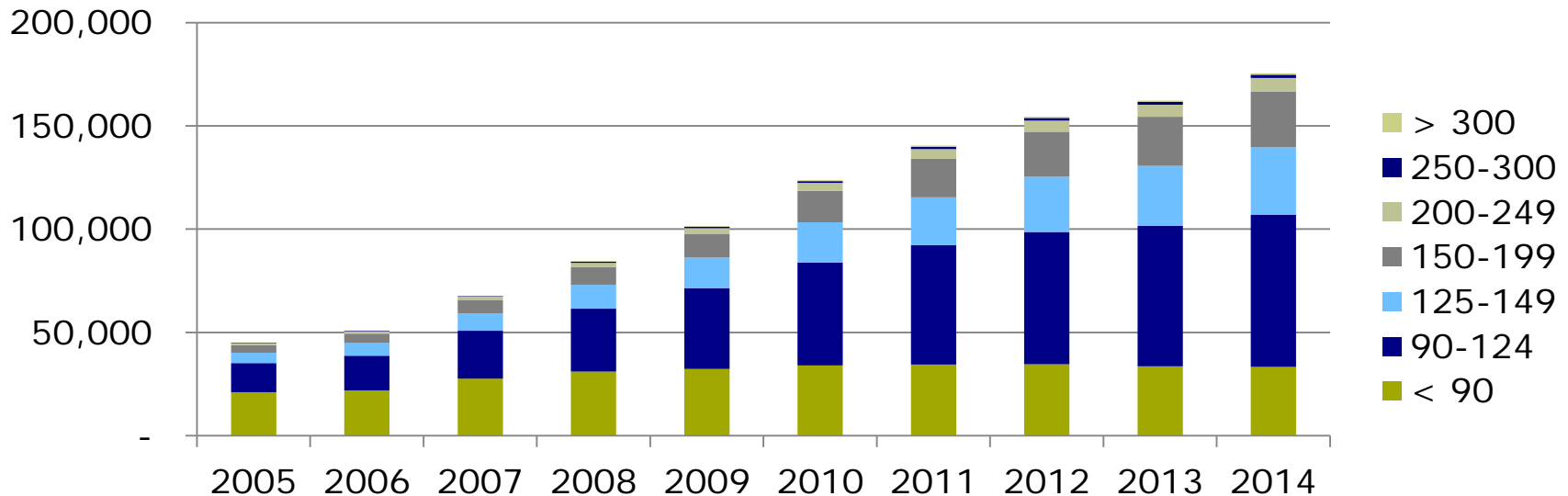
Social: Be The Match® Patient and Health Professional Services

- Confidential one-to-one support and navigation
- Tailored educational materials
- Financial resources
- Fundraising information
- Insurance appeals
- Peer-to-peer connection
- Caregiver support



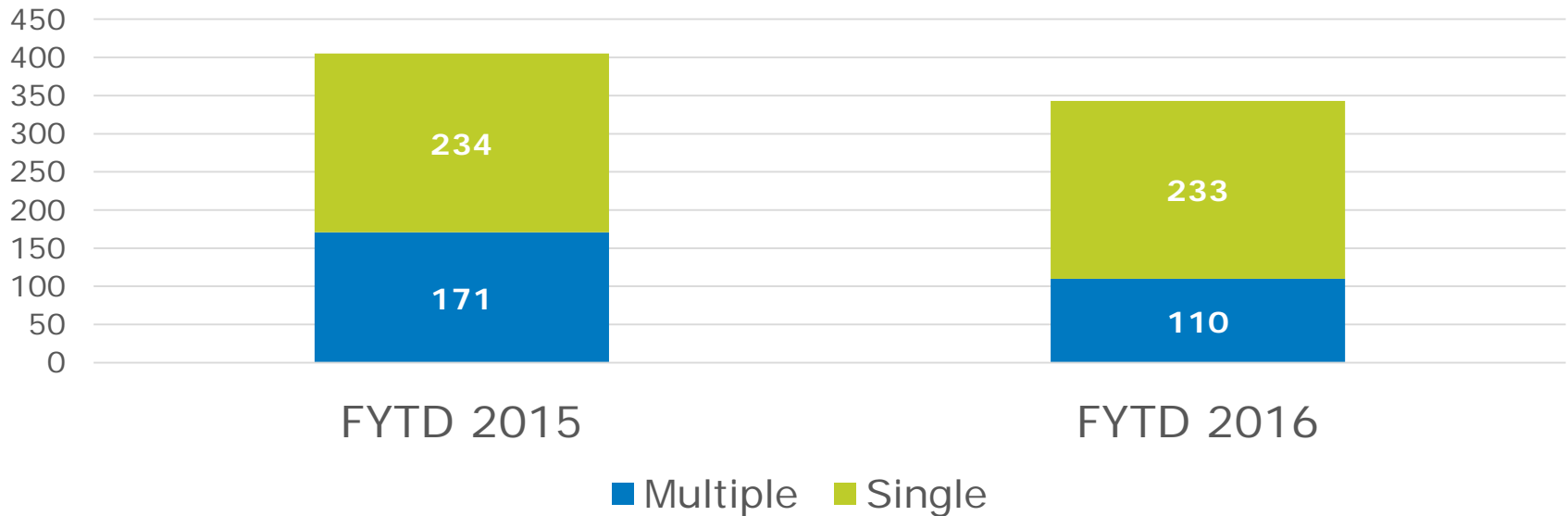
Jill, MSW, LICSW,
Lead Patient Services Coordinator

Historical CBU Inventory by Total Nucleated Cell (TNC) Count



- Medical practice has changed since funding began
- Increasing utilization of higher TNC units
- Higher costs to obtain quality, high TNC unit

Decline in Multiple Cord Blood Unit Transplants



- Declining use of multiple cord blood units for transplant
- Efficiencies realized by high TNC products
- Increase in haploidentical transplants for older patients

Cord Blood Bank Network

Strategically provide funding to support:

- Collection of units in diverse markets
- Collection of high quality, high total nucleated cell count units
- New indications for Cord Blood Transplant
- Transplant outcomes research

Access to Transplant Summary

- The cord blood bank network provides increased access to transplant
- Access has improved across all ages and ethnicities
- An unmet patient need still exists, especially for people of color
- Haploidentical transplants are increasing rapidly; long term outcomes are unknown
- Maintaining a robust network of cord blood banks is critical

COPPERSMITH

BROCKELMAN

LAWYERS

***Legal Restrictions in Distributing
Cord Blood for Research***

Kristen Rosati

Coppersmith Brockelman PLC

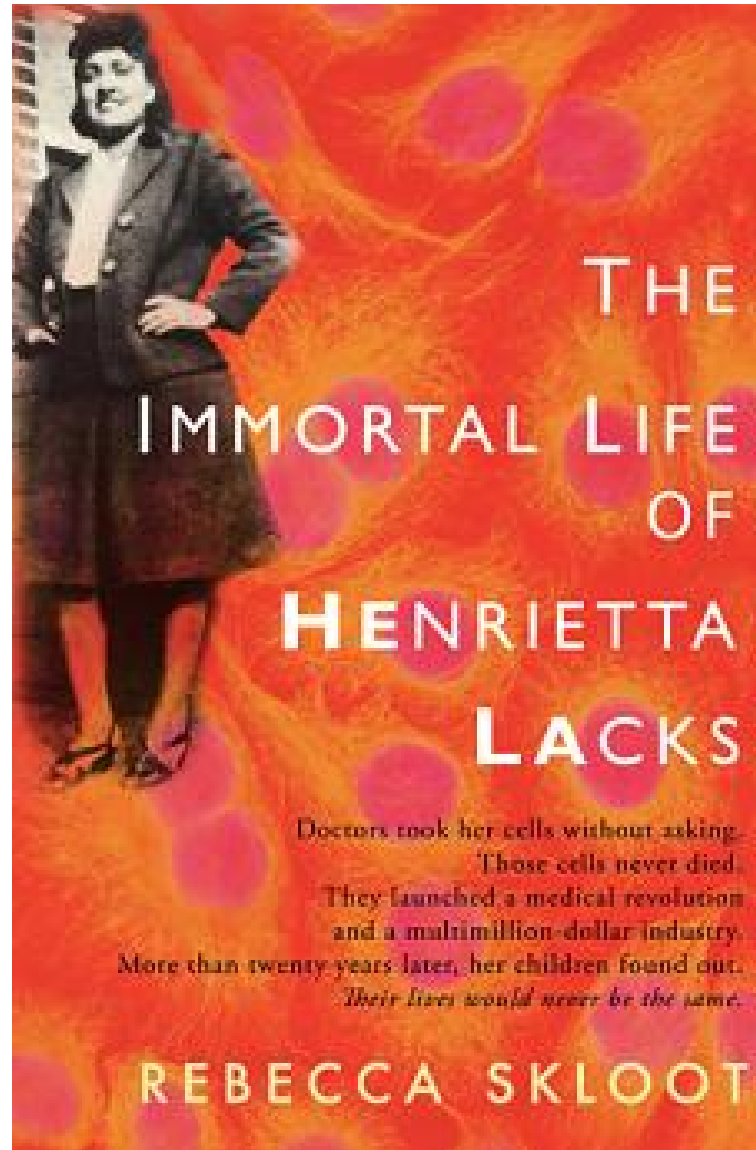
krosati@cblawyers.com

Today's Topics

- Potentially competing policies: advancement of research vs. individual control of tissue and data
- Compliance with the Common Rule
- Compliance with HIPAA
- Compliance with state laws

Potentially Competing Policies

- Advancement of research
 - 21st Century Cures Act
 - Precision Medicine Initiative
 - The Cancer Moonshot
 - Increased funding for NIH
 - The “Learning Healthcare System” (Institute of Medicine)
- Increasing individual control of tissue and data
 - Consent
 - Transparency



Common Rule Compliance

- Applies to “human subjects research” if:
 - Research is conducted or supported by a federal department or agency that has adopted the Common Rule (such as HHS)
 - Where the institution engaged in the research has agreed to apply the federal regulations under the institution’s Federal wide Assurance (“FWA”) to all human subjects research regardless of the funding source

Common Rule Compliance

- It is only “human subjects” research if the activity:
(1) obtains data through intervention or interaction with an individual; or (2) involves identifiable private information
- Key points:
 - Common Rule doesn’t presently apply to non-identifiable biospecimens
 - Common Rule doesn’t presently apply to de-identified data

What changes are proposed?

- Notice of Proposed Rule Making, 80 Federal Register 53933 (September 8, 2015)
- Sweeping changes proposed to the Common Rule:
 - Expands jurisdiction: would apply to all non-FDA regulated, non-exempt and non-excluded human subjects research conducted at a US institution that receives federal support for human subjects research, regardless of funding source for particular research

What changes are proposed?

- Changes the definition of “human subjects” to include non-identifiable biospecimens
 - Will apply prospectively only, three years after the final rule is published
- Requires “broad” consent for biospecimen collection and use for research
 - Will exclude research that generates information already known about an individual for validation testing and development of diagnostic tests
- Requires notification if non-identifiable information could be used for future research without additional consent

What changes are proposed?

- Other proposed changes to informed consent:
 - Changes to the organization of informed consent documents
 - Informed consent for federally funded research must be posted on a federal website within 60 days after the trial closes to recruitment
 - New informed consent waiver criteria

What changes are proposed?

- Under new data privacy and security standards, institutions and investigators will have the option of:
 - Applying the OHRP-specific measures that would function as a safe harbor (not yet published)
 - Apply the requirements of the HIPAA Security Rule

HIPAA Compliance

- HIPAA applies to “covered entities” and “business associates”
- HIPAA applies to “protected health information” (PHI)
 - Demographic information that includes any listed “identifier”
 - Biospecimens without identifiers are not treated as PHI

HIPAA Identifiers

- Data elements about individuals and their family members, household members, or employers:
 - Name;
 - Street address, city, county, precinct, or zip code (unless only the first three digits of the zip code are used and the area has more than 20,000 residents);
 - The month and day of dates directly related to an individual, such as birth date, admission date, discharge date, dates of service, or date of death;
 - Age if over 89 (unless aggregated into a single category of age 90 and older);
 - Certain numbers related to an individual (telephone numbers; fax numbers; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers, serial numbers, and license plate numbers; device identifiers and serial numbers);
 - Email addresses, Web Universal Resource Locators (URLs) and Internet Protocol (IP) addresses;
 - Biometric identifiers, such as fingerprints;
 - Full-face photographs and any comparable images; or
 - Any other unique identifying number, characteristic, or code.

De-identification of PHI

- OCR guidance on de-identification at <http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.html>
 - “Safe Harbor” method
 - Removal of all HIPAA “identifiers”
 - “Expert Determination” method
 - Determination that there is a “very small” risk that the anticipated recipient will be able to identify an individual

- De-identification through coding: HIPAA-compliant code may not be derived from individual identifiers (i.e. no initials, scrambled SSN or medical record number, etc.)

HIPAA Privacy Rule Compliance

1. The research involves only de-identified data
2. The research uses or discloses a “Limited Data Set” (mostly de-identified data) and the covered entity has a “Data Use Agreement” in place with the recipient of the Limited Data Set
3. The research subject or the subject’s authorized representative has signed a written HIPAA authorization
 - If PHI will be used or disclosed in future research, must describe with enough detail so that a person will understand this
4. An IRB has waived the requirement for authorization
5. The activities are just to prepare for research and required representations are obtained from the researchers

HIPAA Privacy Rule Compliance

6. The use or disclosure is for patient recruitment purposes;
7. The research involves only the information of decedents and required representations are obtained from the researchers;
8. The disclosure of the PHI is required by law; or
9. The research is “grandfathered”

State Laws to Watch

- State health information confidentiality laws that regulate “sensitive” information, such as genetic information or HIV status
- State genetic testing laws, some of which apply to genetic testing conducted in research
- State laws governing the ownership of biospecimens or genetic material
- State laws governing the use or sale of human tissue
- State laws related to research participant rights

Questions?

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Program Overview

Jennifer Botsford, ABRC

April 7, 2016



Arizona Biomedical
Research Commission

Grants • Biospecimen Locator • Education • Public Cord Blood



Abrazo™
Central Campus



Dignity Health.
St. Joseph's Hospital and
Medical Center



Tucson
Medical
Center



MIHS
MARICOPA INTEGRATED HEALTH SYSTEM
Maricopa County Special Health Care District



Arizona Biomedical Research Commission

1984

Established
by Statute

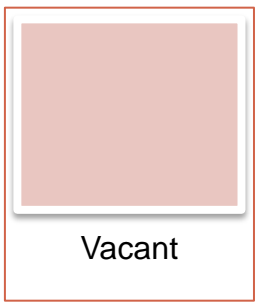
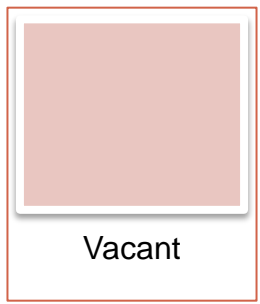
2011

Moved
under ADHS

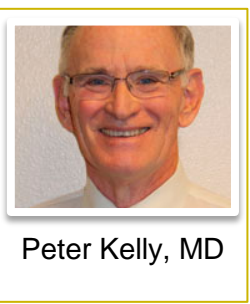
to identify and support innovative biomedical research
to improve the health of all Arizonans

9 Commissioners

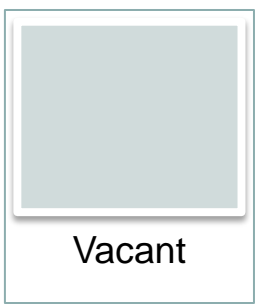
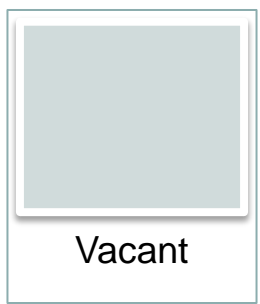
3 Public
Members



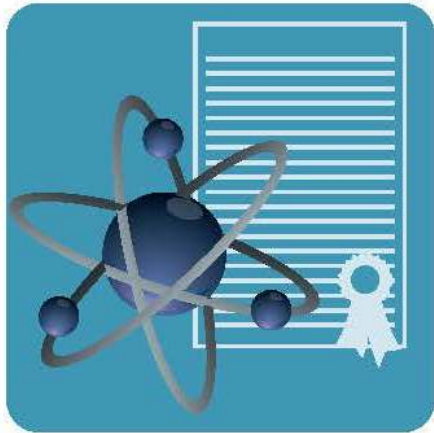
3 Medical
Community
Members



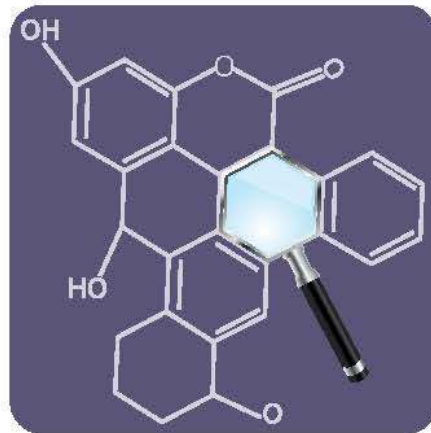
3 Scientific
Community
Members



4 Core Programs



Research Grants



Biospecimen Locator



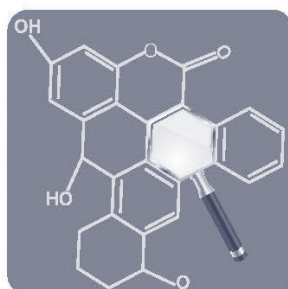
Research Education



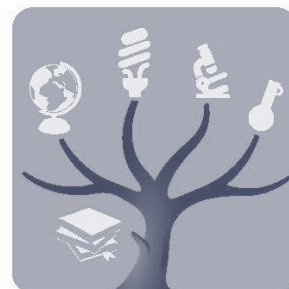
Public Cord Blood



Research Grants



Biospecimen Locator



Research Education



Public Cord Blood



.....Arizona is a leader in the field of public cord blood collection

Statute § 32-3212

- 2007
- OB providers required to educate expectant parents about saving cord blood
 - Public donation
 - Private banking
- Distribute ADHS brochure





Arizona
PUBLIC
CORD BLOOD PROGRAM



Established by ABRC in 2011



Funded through Lottery Revenue

- Disease Control Research Fund



Reimbursement from transplanted
cords



Why Donate Cord Blood?

7

out of 10 patients **lack a** family bone marrow **match**

\$0

Free to Donate

80+

Diseases can be **treated or cured** using cord blood



Non-transplantable units made available for **research**, with consent



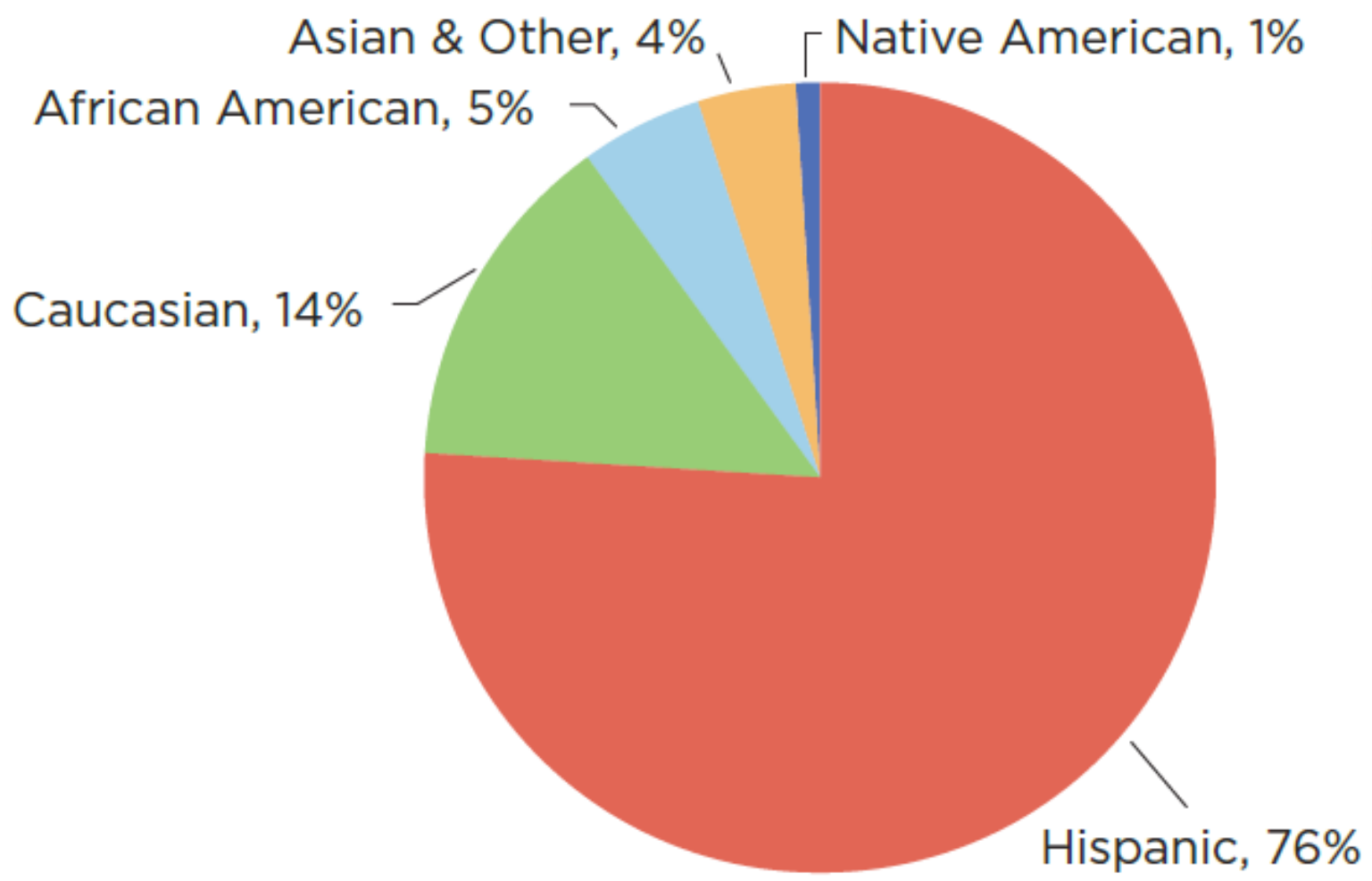
Why Collect in Arizona?



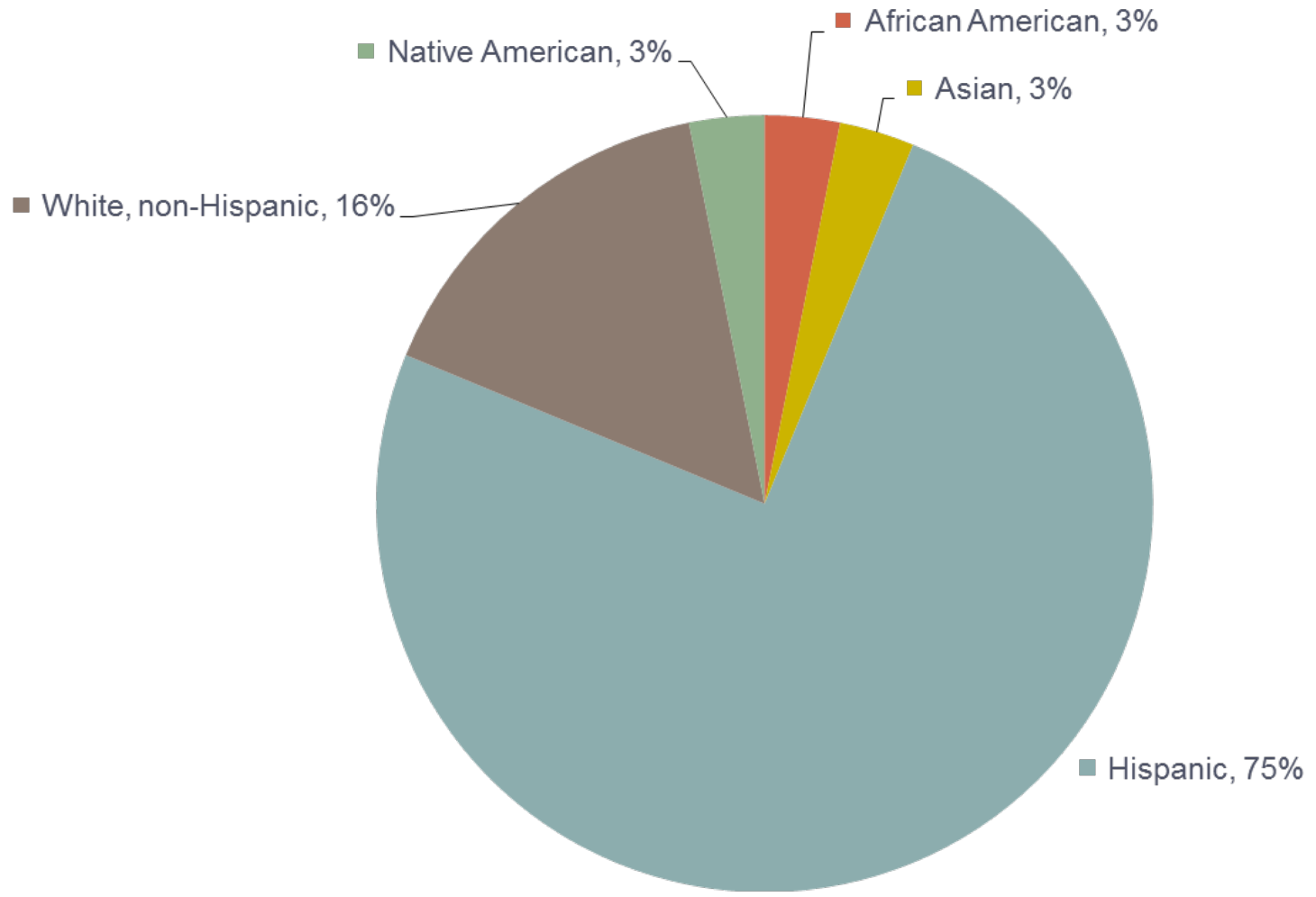
↑ **diverse registry =**
↑ **chance of a match**

- ✓ Unique gene pool
- ✓ 86% of cord blood units collected in Arizona are from **minority donors**
- ✓ 77% of AZ cord blood units used in transplants are for **minority patients**

Arizona Ethnicity Summary Data for Total Units Collected



Race/Ethnicity Cord Blood Units Used in Transplants



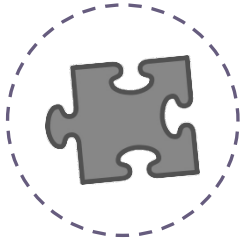
Benefits to Arizona



Advocate for and address the needs of underserved citizens



Increase **awareness** of public cord blood banking



Resource for AZ researchers



Attract cellular, biomedical, and technology **businesses** and organizations to strengthen the **local economy**



What do we do?



Collect and store cord blood



List cord blood units on national and international registries



Educate:



Expectant
parents



Health
professionals



Public



Next
generation



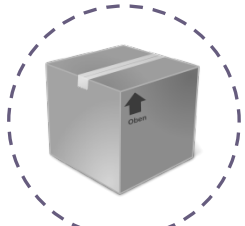
Process



Obtain patient's written consent



Between birth and delivery of placenta, OB provider collects into bag



Send to cord blood bank



Process, test, validate



Cryopreserve (freeze) within 48 hours



.....Cord blood is some patients' best or only **hope**

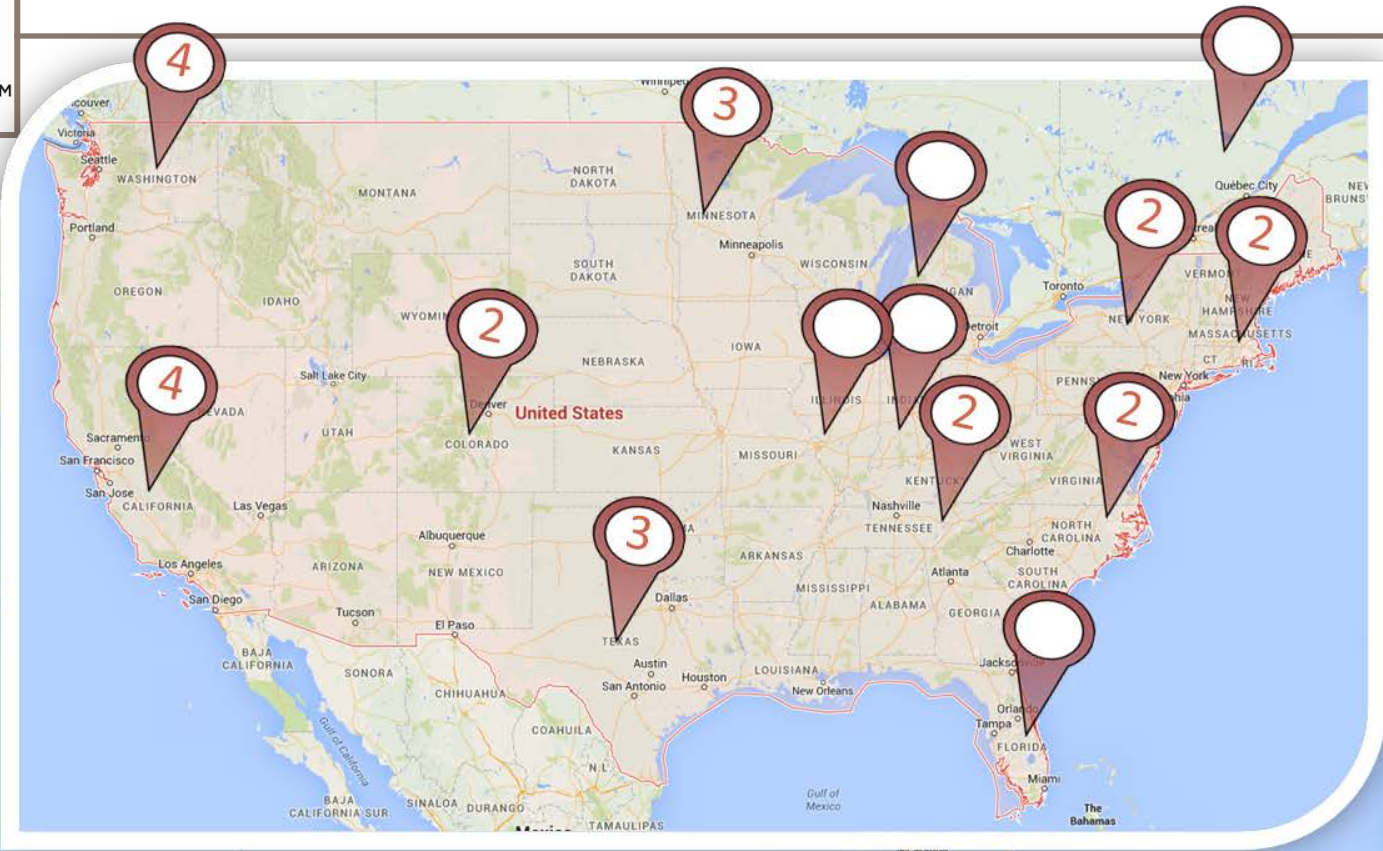
30+

Arizona cord blood units used for **transplants** around the world

600+

Arizona cord blood units **banked** and **registered** with the National Cord Blood Inventory





Why is APCBP Successful?



Partner hospitals

- Nurse coordinators
- Consenters



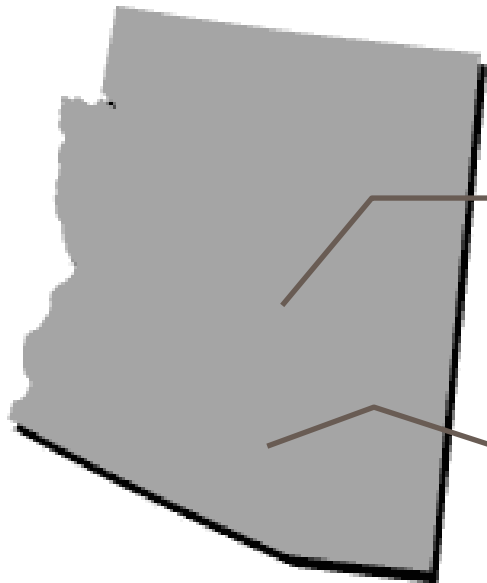
Local non-profit



Accredited cord blood bank



Nurse coordinators



Central Arizona

(St. Joseph's Hospital and
Medical Center)

Southern Arizona

(Tucson Medical Center)

- **Train** consenters in partner hospitals
- **Coordinate** education, outreach, and overall collection management





- Partners with the nurse coordinators
- Educates and outreaches
 - OB providers
 - Next Generation
 - Community Leaders
 - General public



Consenters

- Placed in partner hospitals
- Answer questions one-on-one and consent moms-to-be
- Present in the delivery room to answer questions and guide new collectors



Cord Blood Bank

- ClinImmune, University of Colorado
 - Accredited by AABB, FACT
 - Test, process, and validate cord blood units
 - Store cord blood units
 - Coordinate with donor hospitals, national and international registries, and recipient hospitals
 - Train AZ hospitals



Partners



Arizona Biomedical
Research Commission

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Abrazo™
Central Campus



Tucson
Medical
Center



Dignity Health
St. Joseph's Hospital and
Medical Center





EXTRA! EXTRA!

Abrazo Central Campus reaches out to families and nursing school students

- Joined APCBP in 2011
- 1st cord blood collected by the program was collected at Abrazo Central Campus

- Families learn
 - Stem cells
 - Arizona Public Cord Blood Program
- Consenter educates local nursing school students



EXTRA! EXTRA!

Maricopa Integrated Health Systems

building strategy to reach minority mothers through pre-natal classes

- Joined APCBP in 2011
- 2 cords in 2015 were used in transplants to save lives

- New marketing strategy
 - Include APCBP information in pre-natal classes
 - More time to consider donating
 - Ability to consider before they are in labor



EXTRA! EXTRA!

St. Joseph's Hospital and Medical Center collects the most transplanted cord blood

- Joined APCBP in 2011
 - 2000+ collections
 - 20+ CBUs sent for transplant
- St. Joe's consistently collects **high volume** cord blood units
 - more likely to be banked
 - more likely to be transplanted



EXTRA! EXTRA!

Baby delivered at **Tucson Medical Center** helps save Colorado Patient's life

- Joined APCBP in 2014
- 2 consenters and 1 nurse coordinator
- 1st cord for transplant was sent this year

“I was so excited to learn that one of our cord blood units was used for transplant! It is so encouraging to know that the selfless generosity of this donor family combined with our efforts has made all the difference in the world to a leukemia patient and their family. The positive ripple effect our program creates is truly immeasurable, and I’m looking forward to more matches in 2016.”

- TMC consenter Ali Baker



EXTRA! EXTRA!

Save the Cord Foundation speaks with National Association of Hispanic Nurses at the 2nd Annual Conference, Phoenix Chapter

- Joined APCBP in 2013
- **Thousands** of OB professionals educated
- **Thousands** of students educated

- Educated new & experienced nurses
- Received enthusiastic feedback
- Facilitated new contacts
- Increase minority donations



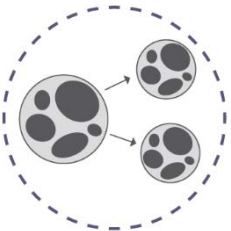
EXTRA! EXTRA!

ClinImmune, University of Colorado sends 32nd Arizona cord blood unit for transplant

- AABB certified
- FACT certified
- Partnering with AZ since 2011

- Moves to new upgraded state-of-the-art facility
- Banked over 600 Arizona cord blood units

Key Messages



Blood left in the umbilical cord **after a baby is born** is a unique source of **life-saving** stem cells



The baby and the mother **are not harmed**



Historically, considered **medical waste**



Today, **collected and stored** around the world, both privately and publicly



Stem cells

I don't know how to multiply!



It's easy, silly, just divide!





Arizona Biomedical Research Commission

Victor Waddell, Executive Director • Jennifer Botsford, Program Manager • Theresa Napoleon, Program Coordinator

(602)364-0157 • CordBloodInfo@azdhs.gov

www.azdhs.gov/biomedical/#az-public-cord-blood-program



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St. Joseph's Hospital and
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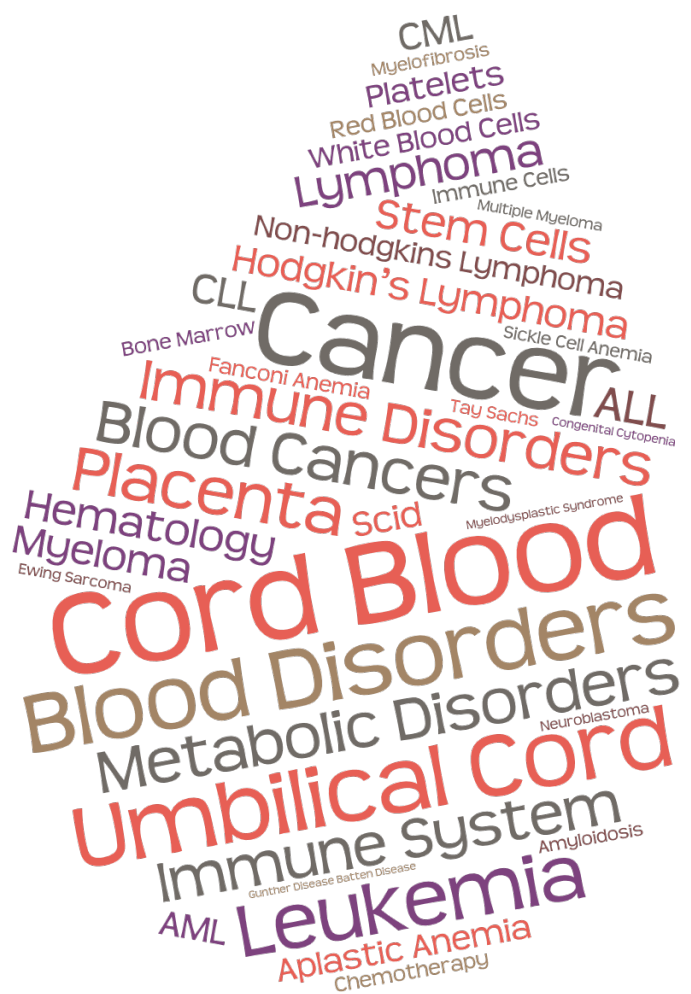
Tucson
Medical
Center



MIHS
MARICOPA INTEGRATED HEALTH SYSTEM
Maricopa County Special Health Care District



Questions?



Thank you!



Cord Blood Education, STEM Careers & the Next Generation

Charis Ober
Executive Director
Save the Cord Foundation



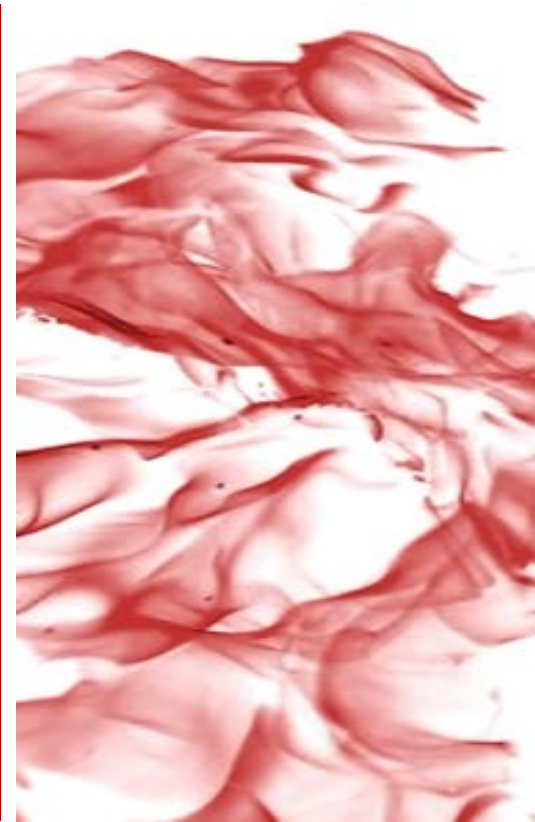


Arizona Biomedical
Research Commission

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Partners in Advancing Public Cord Blood Donation and Education



“Education is the most powerful weapon which you can use to change the world.”

–Nelson Mandela

STEP ONE: Awareness and Education.

Without awareness and education nothing happens.

Who

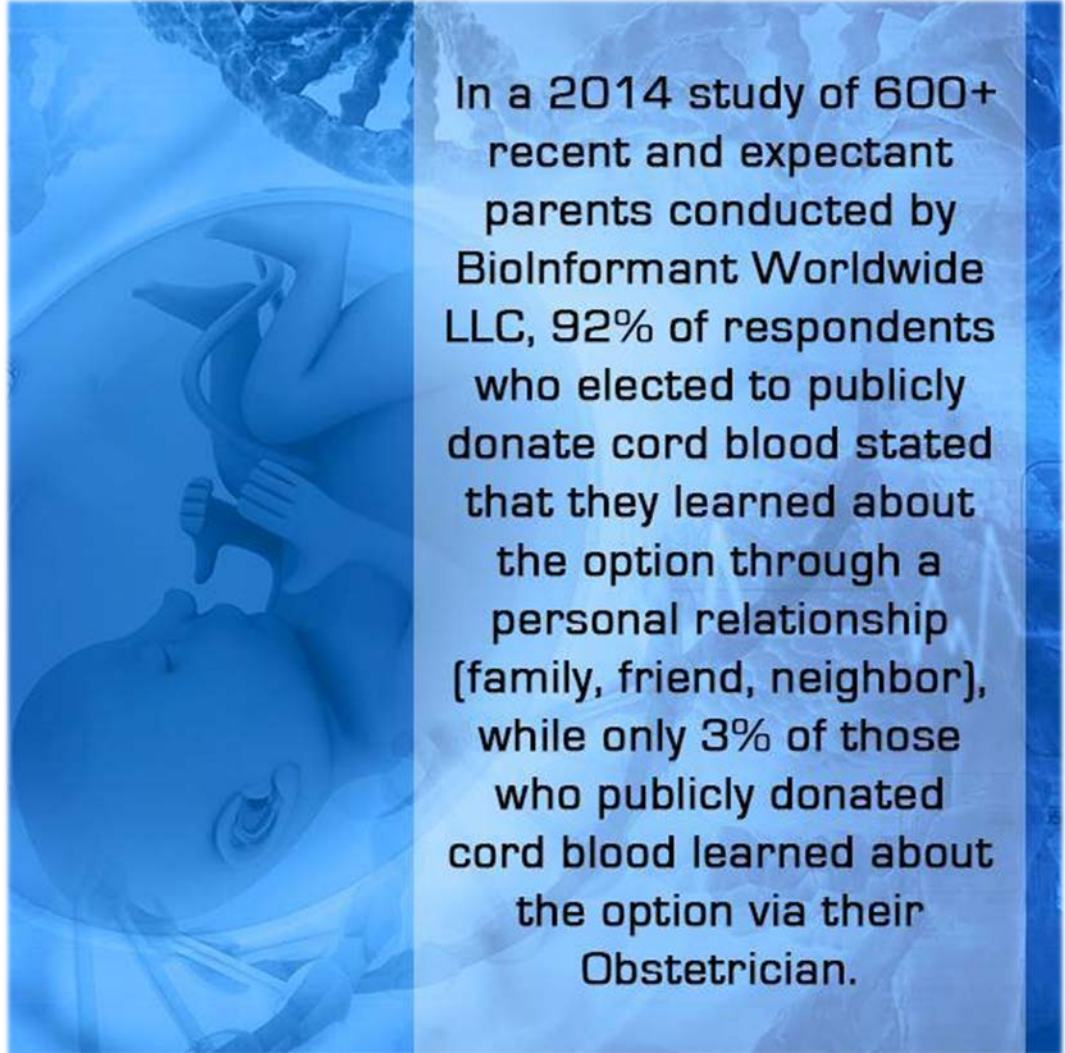
- Expectant Parents
- Health Professionals
- The Public
- The Next Generation



Expectant Parents



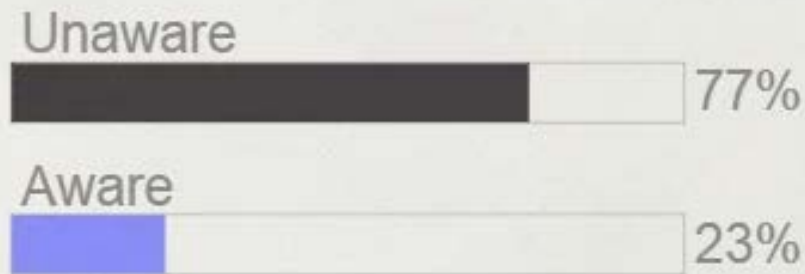
Parents Amy Vasquez and Chris Colbert with their daughter, who was the 1000th cord blood donor in Arizona at TMC



In a 2014 study of 600+ recent and expectant parents conducted by BioInformant Worldwide LLC, 92% of respondents who elected to publicly donate cord blood stated that they learned about the option through a personal relationship [family, friend, neighbor], while only 3% of those who publicly donated cord blood learned about the option via their Obstetrician.

Lack of Awareness: A Major Problem for Cord Blood Preservation

In a recent study of 600+ recent and expectant parents by BioInformant Worldwide LLC, a research firm specializing in stem cell data, 77% of respondents who did not store cord blood (publicly or privately) stated that it was because they did not know it existed as an option [6].



Respondents Who Did Not Store Cord Blood

Important Statistics

- U.S. parents privately store cord blood for approximately 2.6% of births

(102,000 / 3,945,000 births = 2.6%).

- If publicly donated cord blood is included too, then approximately 3% of U.S. parents store cord blood at birth

(There are about 5 cord blood units privately stored for every cord blood unit that is publicly donated)

Education Outreach to Health Professionals Physicians, Midwives, Nurses, & Researchers



Left: Arizona Perinatal Trust promotes public cord blood donation & the AZ PCBP



Above: Jennifer Botsford at the University of Arizona Collaborator Fair

Right: CAPPA childbirth professionals learning about cord blood & AZ PCBP





Hispanic and Minority Outreach



National Association of
Hispanic Nurses Learns
about Cord Blood
& the Arizona Public
Cord Blood Program



The General Public

- July: Cord Blood Awareness Month in Arizona
- Cord Blood Conference on April 7th
- Public information and education via media partnerships
- AZPCBP brochures and posters for expectant parents, OB providers, midwives and the public



Our Education Partners



NEXT GENERATION: Student Education Outreach

- Elementary, Middle, and High School Programs
- Next Generation Cord Blood Education Program developed with teaching faculty
- Inspiring the next generation of scientists, engineers, and problem solvers!
- STCF Intern program at key Arizona universities















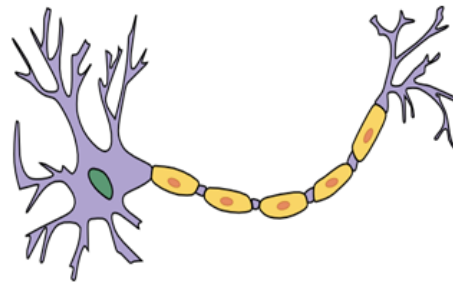
Autism and Brain Disorders



Dr. Joanne Kurtzberg (MD)
Dr. Geraldine Dawson (PhD)



- Developing cell-based therapies to restore damaged areas of the brain
- Cord blood stem cells to treat autism, cerebral palsy, and stroke



Autism and Cord Blood Stem Cells: FDA Gives Green Light for Groundbreaking Clinical Trial

SACRAMENTO, CA – Sutter Neuroscience Institute, a recognized Center of Excellence, and CBR (Cord Blood Registry), the world's largest stem cell bank, are launching the first FDA- approved clinical trial to assess the use of a child's own cord blood stem cells to treat select patients with autism. This first-of-its-kind placebo controlled study will evaluate the ability of an infusion of cord blood stem cells to help improve language and behavior. The study is in conjunction with the Sutter Institute for Medical Research.

UCB stem cells rebuild the blood and immune systems

"We have evidence to suggest that certain children with autism have dysfunctional immune systems that may be damaging or delaying the development of the nervous system"

–Dr. Chez

Hearing Loss

Cord Blood Stem Cell Infusion for Children with Acquired Hearing Loss



- Investigating whether cord blood stem cells repair hearing loss
- Hearing ability affects your language development
- Can lead to poor academic and social development

Diabetes

Four-year-old girl makes history in world-first attempt to prevent type 1 diabetes

Amy Corderoy



- Isla Robinson: 1st child given her own cord blood to prevent type 1 diabetes
- Researchers hope the immune cells in her umbilical cord blood will reboot her immune system and prevent the damage of insulin producing cells

STCF Internship Program and The Next Generation

- Student outreach by STCF Interns at the University of Arizona, ASU and NAU
- Cord blood Education in the classroom, on campus and with other organizations
- Creating STEM careers

Raising cord blood
awareness & research
at the U of A



Educating young scientists at
AZ Stem Adventure



Tanque Verde Elementary
School students learn about
cord blood



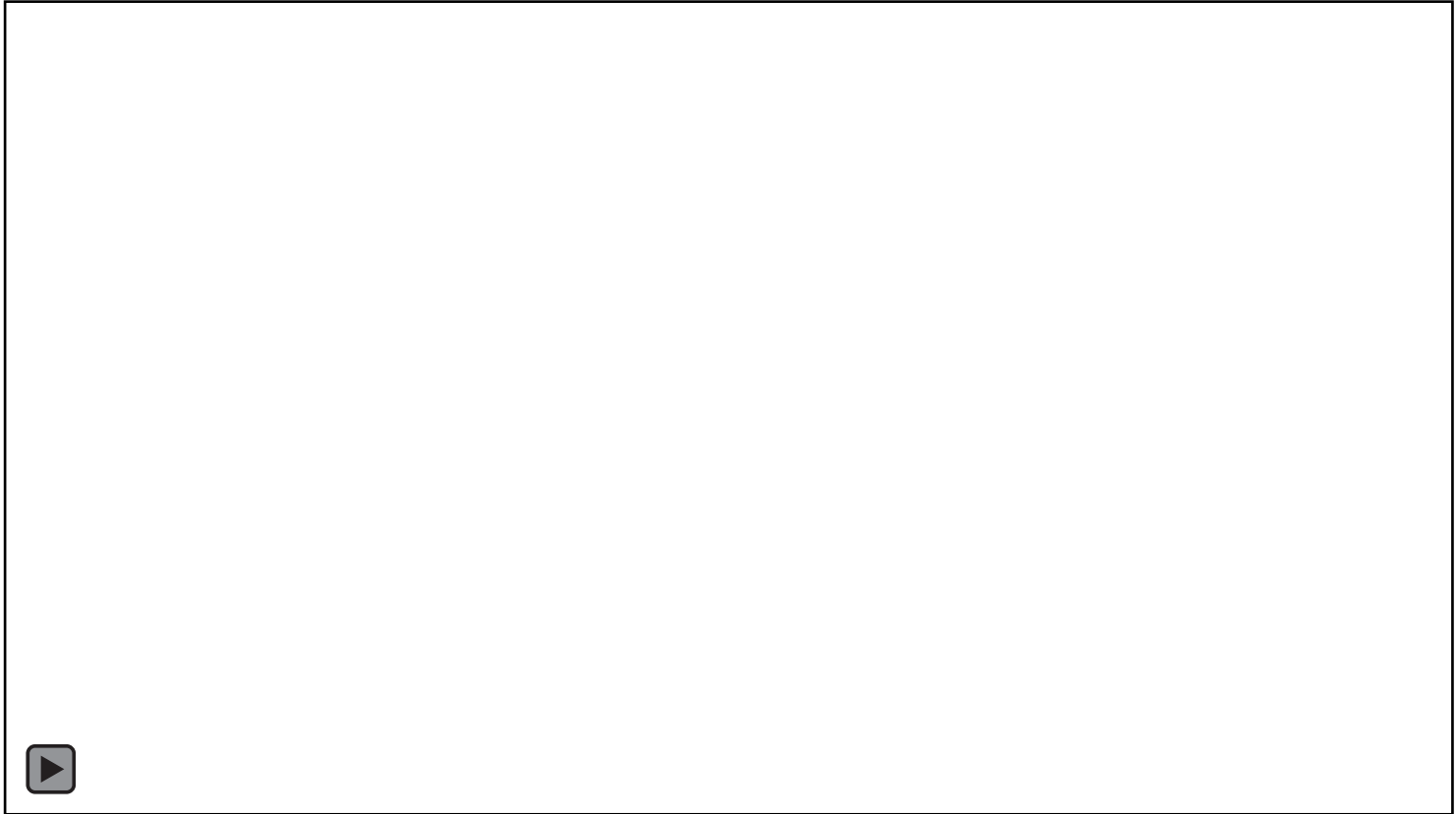


NEXT GENERATION: Cord Blood



▶ ⏮ 🔊 1:36 / 2:13 ⚙️ 🖥️ 🗑️

NEXT GENERATION: Cord Blood



[VIDEO LINK \(optional\)](#)

The Big Picture for Our State

- **Expand cord blood donation** across our state
- Make **cord blood education a standard** in our classrooms
- Fund and encourage important **stem cell research** at AZ universities
- Continue important legislative **funding** so the Arizona Public Cord Blood program will become a legacy health initiative to serve the underserved of our state
- **Attract cellular, Bio and Pharma businesses** that provide a scientific business platform for science-based careers

The 6th C's of Arizona

It's Cells.... Stem cells are the medicine of the future and good business for our state!

Cattle

Cotton

Climate

Citrus

Copper

“The future depends on what we do
in the present.”

–Mahatma Gandhi

Education is the key!



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Cord blood treatment from the physician's perspective

Dr Niketa C Shah MD

Bone Marrow Transplant Physician
Center for Cancer and Blood Disorder
Phoenix Children's Hospital

Assistant Professor of Pediatrics
Department of Child Health
University of Arizona

Introduction

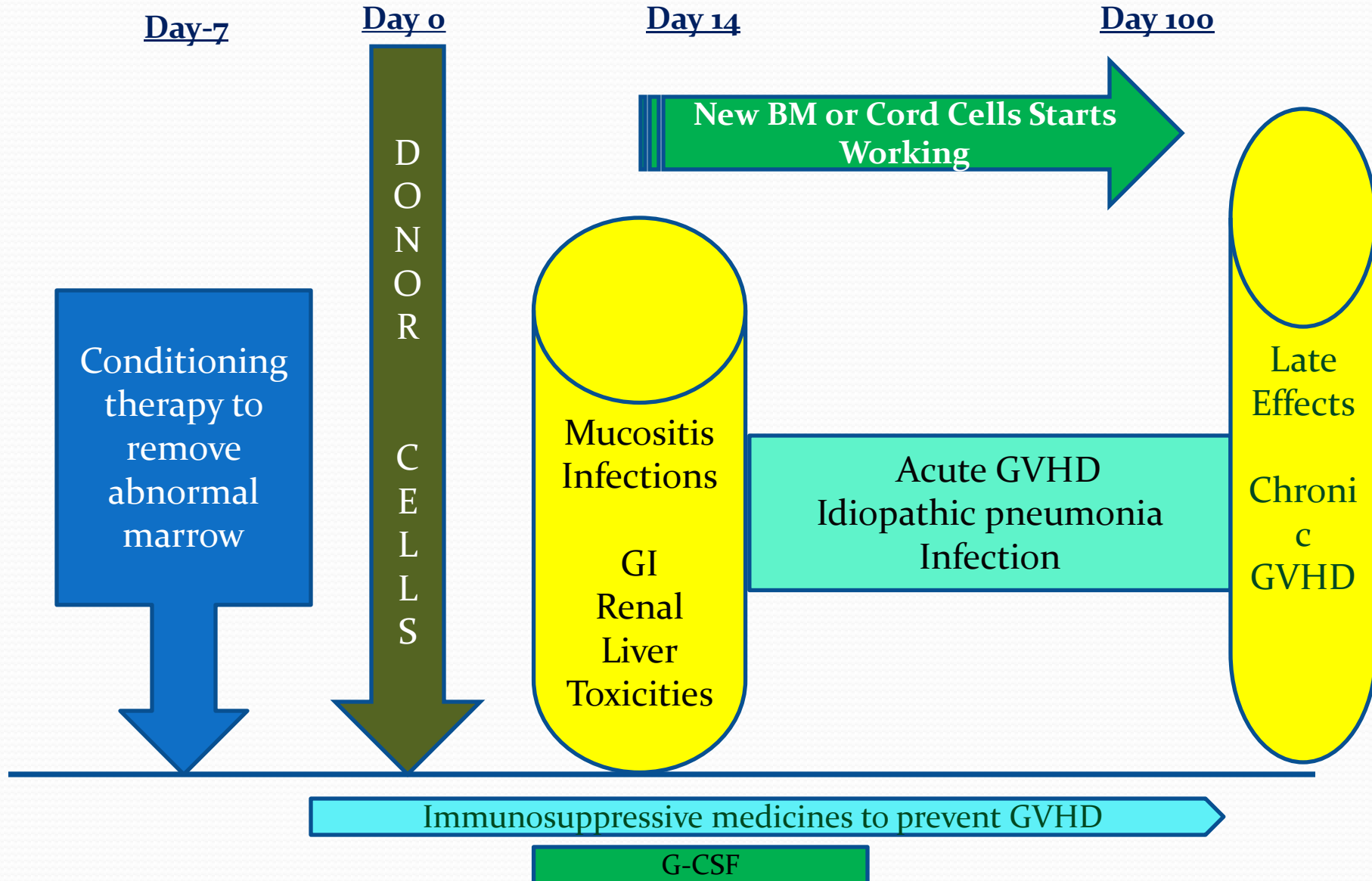
- What is a bone marrow or cord transplant?
 - Healthy bone marrow and blood cells are required to live.
 - Many disease affects bone marrow so that it cannot function properly.
 - Congenital
 - Acquired
 - A marrow or cord blood transplant could be the best treatment option.
 - For some patients, it may be the only potential cure.

Introduction

Donors for stem cell transplant

- Matched siblings or matched related
- parents or siblings for haplo-identical
- Matched or Mismatched unrelated
 - A; living adult volunteers (BM or PBSC)
 - B; umbilical cord blood units.

Dynamics of Bone Marrow or Cord Transplant



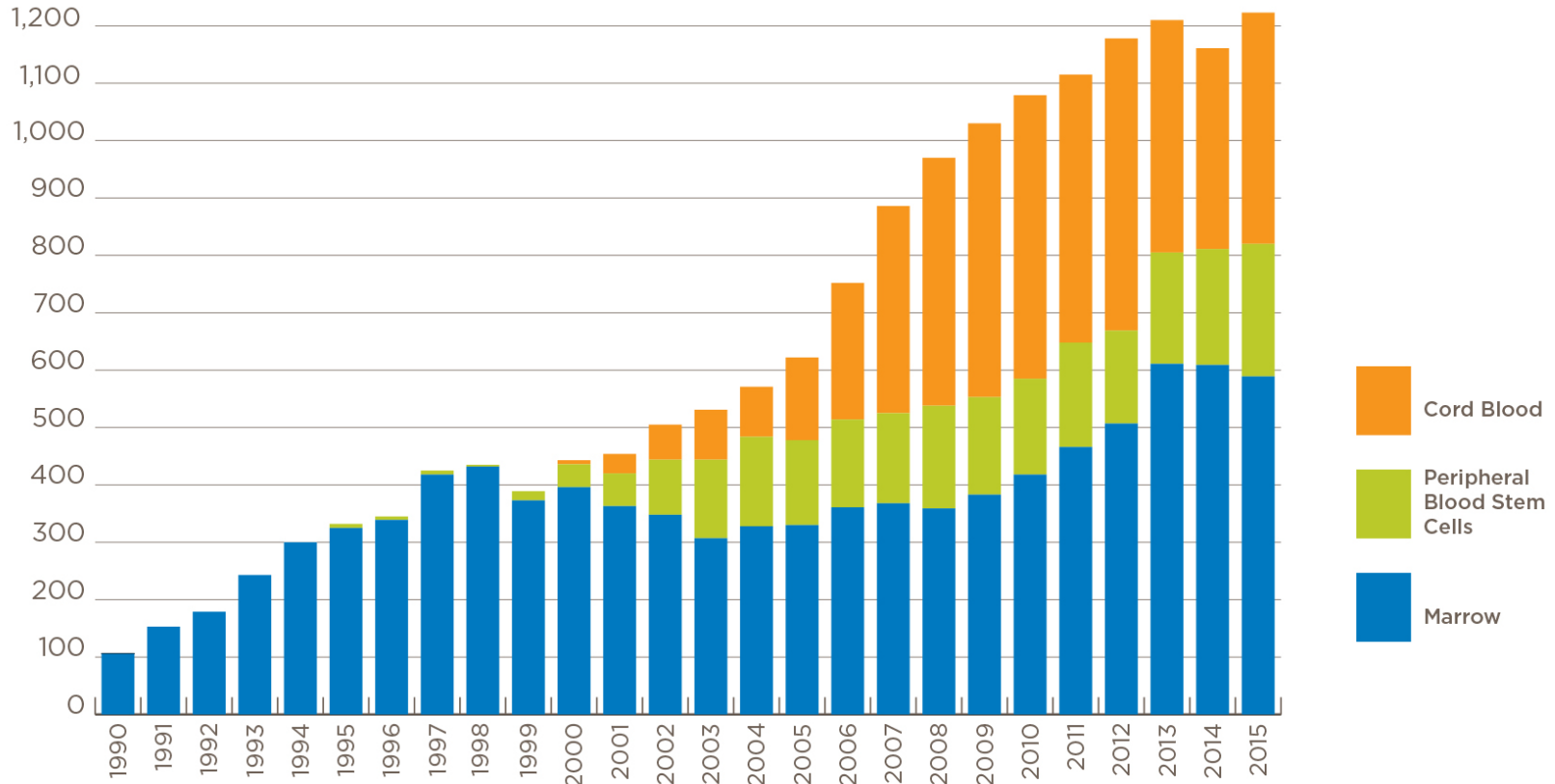
Difference Between Unrelated BM/PBSC graft Vs Unrelated Cord Vs Haplo identical

	Unrelated BM/PBSC	Cord	Haplo-identical
Availability	2-3 months	No wait time 1-10 days	No wait time 1-10 days
Viability	BM -Hours PBSC-Months	Cryopreserved for years	BM -Hours PBSC - Months
Donor Discomfort	Yes Anesthesia, Surgery, G-CSF	No	Yes Anesthesia, Surgery, G-CSF
HLA Matching	Near match or fully match 8-10/10	Mismatch possible 4-6/6	Half match
Risk of Transplanting Genetic Disease	None	Small possibility	None
Stem cell Boost	Available for second donation later	None	Available for second donation later
Extra Cost	Can be costly harvest	Cost of the cord	Can be costly for T cell depletion

Difference Between Unrelated BM/PBSC graft Vs Unrelated Cord Vs Haplo identical

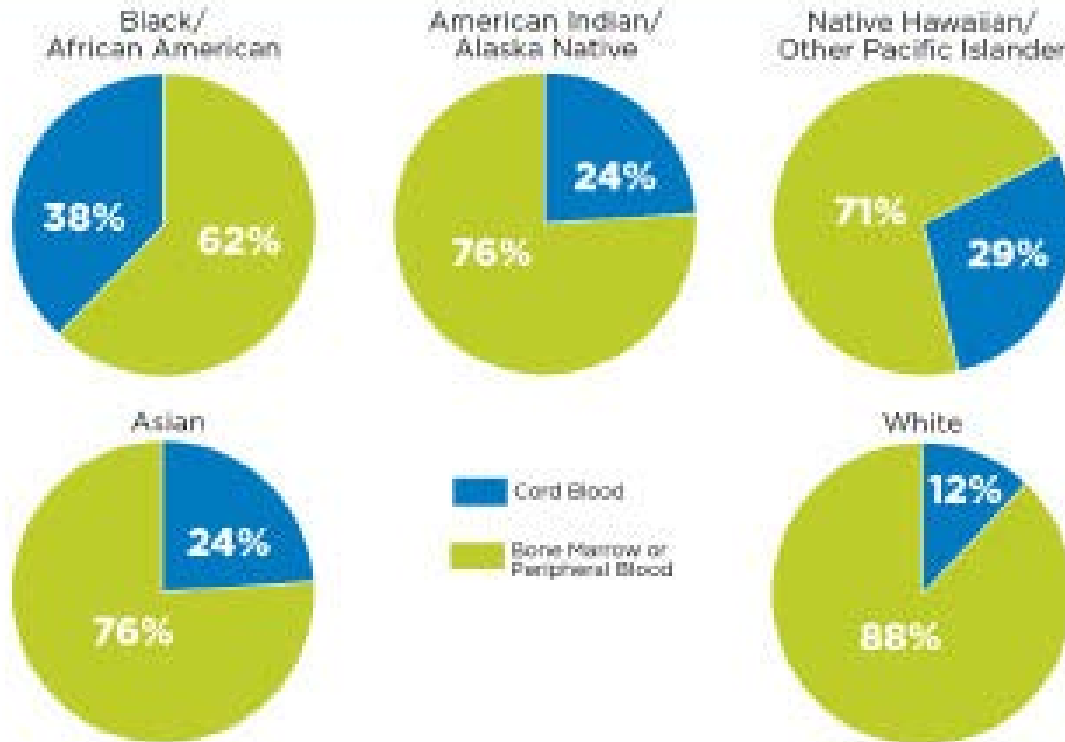
	Unrelated BM/PBSC	Cord	Haplo identical
Neutrophil Engraftment	Rapid 10-21 days	Slower 3-4 weeks (Except double cord)	Rapid 10-21 days
Immune Reconstitution	Faster	Slower	Slower
Risk of infection post transplant	++	++++	++
Graft Versus Host Disease (GVHD)	Increase with HLA mismatch	Less frequent Less severe	Increase risk
Hospital Stay	GVHD	Slow engraftment Infection	GVHD
Experience	More	More	Less

Transplants by Cell Source



Source: National Marrow Donor Program/Be The Match FY 2015

Role of Cord Blood in Transplants by Patient Race

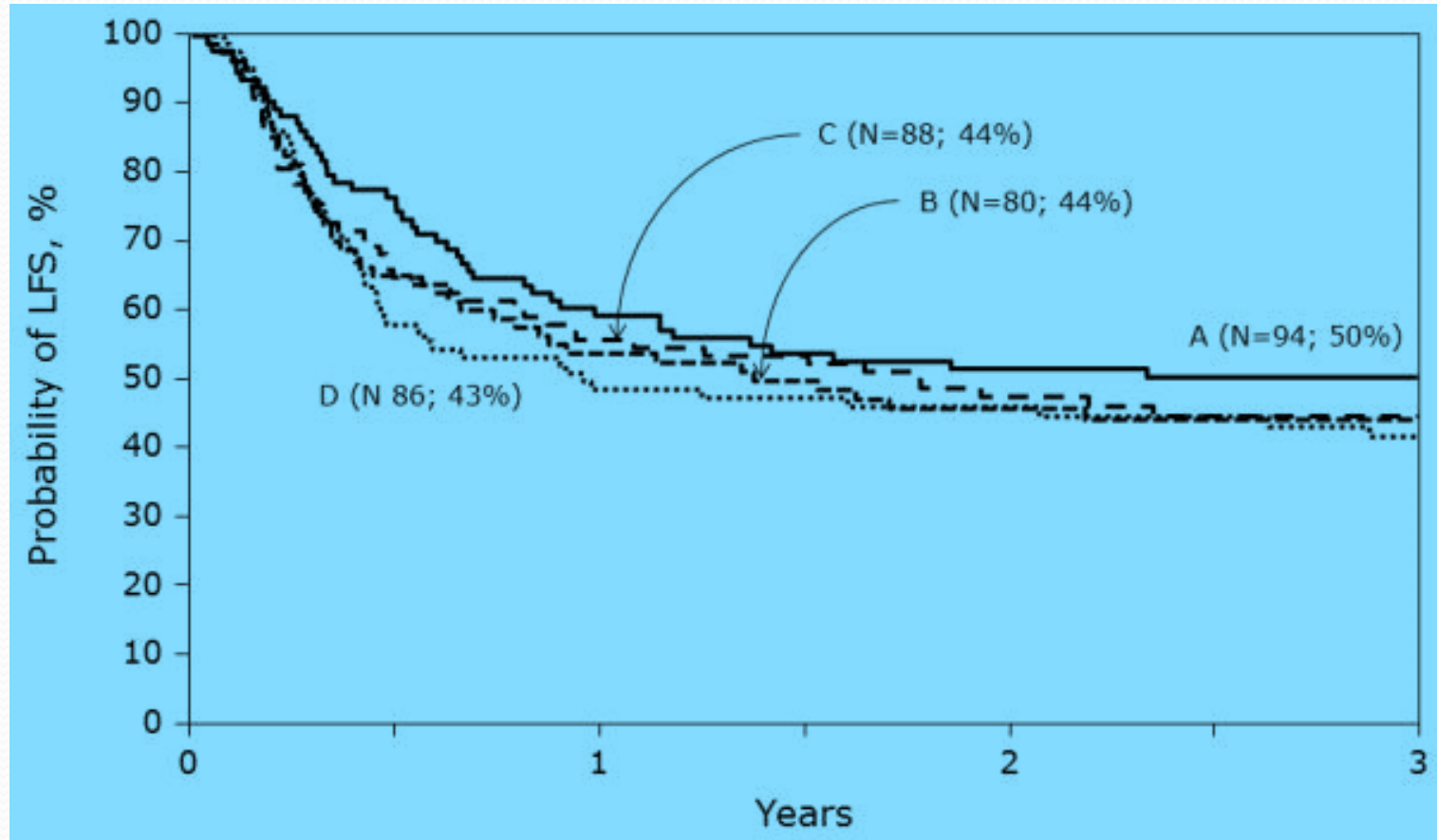


Source: National Marrow Donor Program/Be The Match FY 2018



BE  THE MATCH

Transplant Outcomes based on graft source for Children with High-Risk Acute Lymphoblastic Leukemia- CIBMTR study



Choosing an ideal donor when perfect match does not exist

- Most SCT patients do not have matched sibling or matched unrelated donor.
- Mismatch unrelated donor/cord blood/ haplo identical donor are alternative graft sources
- No randomized trials comparing the outcome of 3 alternative graft source
- Effective lymphohematopoietic reconstitution
- Alternative graft varies
 - time to engraftment , graft failure rate
 - GVHD , Transplant related mortality and relapse risk

Better understanding of these factors help us to select alternative donor



Thank you

