

The Impact of Current Policies for Zika Virus Screening on Accrual to the Carolinas Cord Blood Bank.

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CCBB Background

- **Established in 1997 through the COBLT program**
- **ARC bank 2001-2004**
- **NMDP member bank 2005+**
- **NCBI Cohorts 1 and 5, 2006+**
- **Contract manufacturer for CryoCell (Cord:Use)**
- **BLA – 10/4/2012: DUCORD**
- **Current inventory ~38,000 + ~6,000 CBUUs with a median TNCC of 1.5×10^9**



CCBB Background

- **10 collection sites**
- **Staff, hybrid and “kit” collection models**
- **Automated processing since 2008**
- **Specifications for banking:**
 - 900 million cells post processing
 - Viability 90%
 - CD34 1.25 million
 - CFU growth
 - Negative sterility and donor screening/testing



Types of Consents

■ Full Consent

- 60 to 90 minute process
- Maternal signature

■ Mini Consent

- Gives permission to collect UCB, collect Mom's blood
- Come back later for education, signing of full consent
- Maternal samples not sent and cord blood not processed until Mom signs full consent

■ All Collect

- Yes/No collection at admission or clinic visit
- Full consent if unit meets volume requirements

Donor Screening

- **Donor questionnaire**

- Information about all travel is collected and reviewed

- **Donor testing**

- Hep B Core Ab, Hep B SAg, Hep B NAT
- Hep C Ab, Hep C NAT
- HIV 1/2/O Ab and NAT
- HTLV I/II Ab
- CMV total antibody
- Chagas EIA
- WNV NAT
- Zika NAT (since 1Q 2019)



Look forward program

- **Through the informed consent, mothers grant permission for CCBB to contact them in the future (no time limit) to check on the status of their baby's health**
- **In addition, mothers grant permission to contact the baby's pediatrician via PC or EMR**
- **Mother's are also given stamped postcards, email contact information, phone numbers to contact the CCBB if their baby is sick with a serious illness**



Innovations

- **Formal collection training program**
 - 2 weeks
 - Rex Hospital
- **Flexible staffing models**
- **Grady Hospital collection site**
- **All Collect Model**
 - EPIC consent for collection



Challenges

■ **Licensure**

- Increased costs for BLA
- Increased costs of operations (~11%)

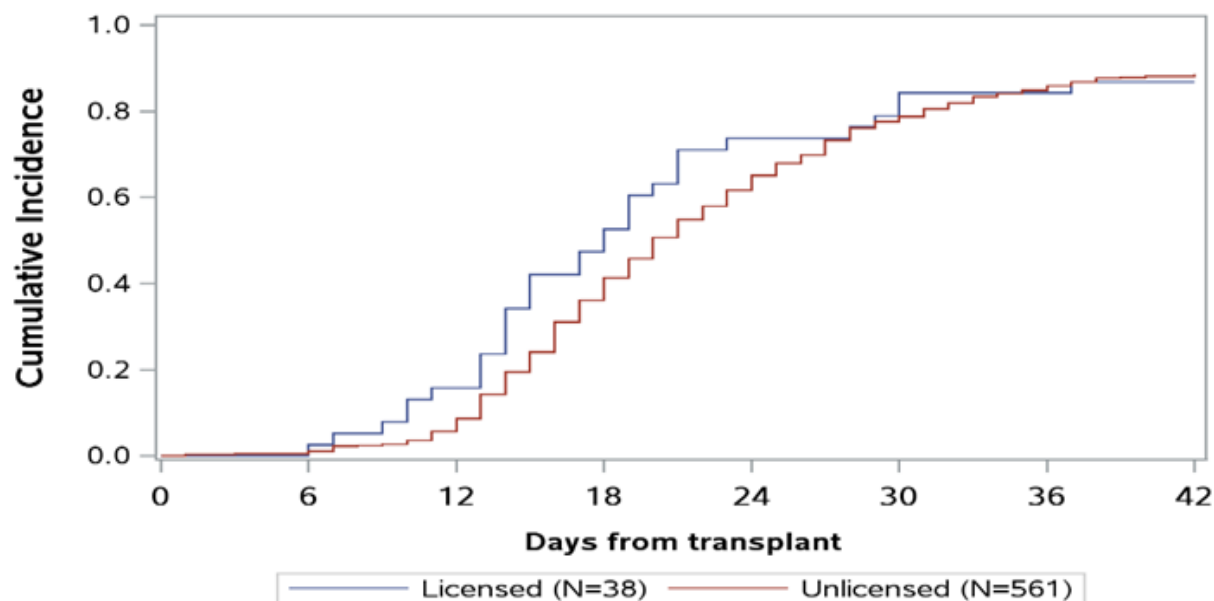
■ **Delayed cord clamping**

- Reduced CB volumes
- Reduced #s of units eligible by TNCC for banking
 - More pronounced effect on AA units

■ **Zika travel risk exclusions**

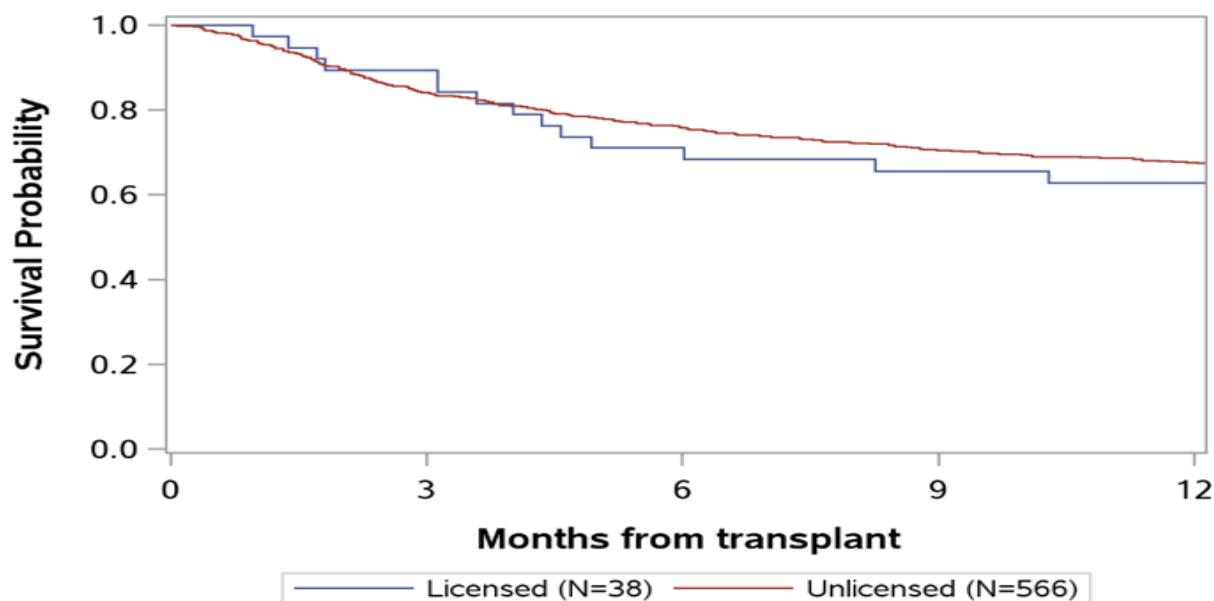
- ~10-25% loss of otherwise eligible units
- FDA allows banking and distribution as ineligible units

Figure 3. Cumulative Incidence of Neutrophil Engraftment for Single Cord Transplants Involving Licensed and IND Units, Performed in US Centers and Having 1 Year Follow-Up



Cumulative incidence estimates (%) and 95% CI at 42 days: Licensed 87 (70, 95); IND 89 (86, 91)

Figure 6: Overall Survival After Single Cord Transplants Performed in US Centers and Having 1 Year of Follow-Up: Licensed vs IND

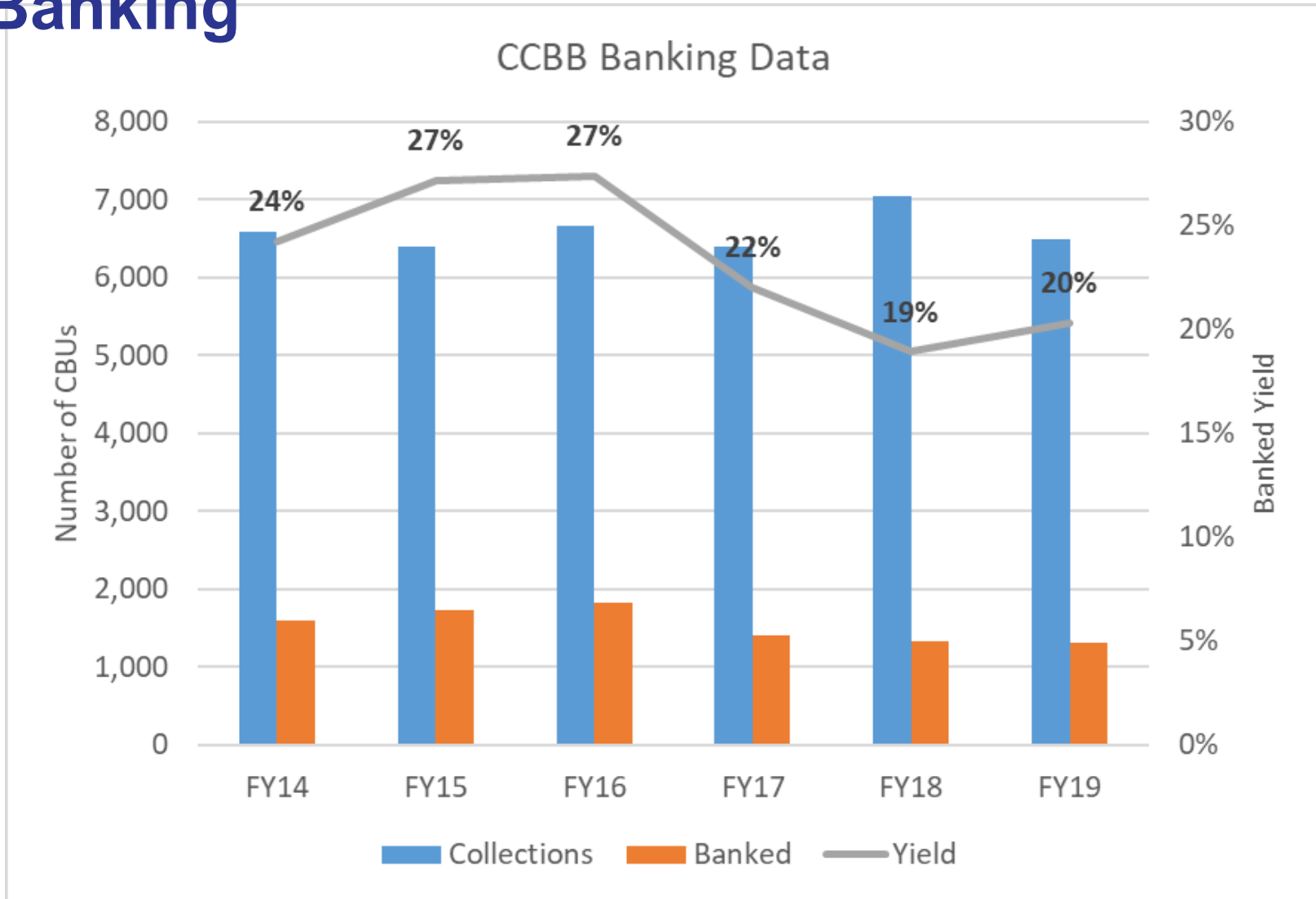


Survival estimates (%) and 95% CI

At 100 days: Licensed 84 (68, 92); IND 83 (80, 86)

At 1 year: Licensed 63 (45, 76); IND 68 (64, 71)

Annual Plan for Recruitment, Collection and Banking



FY = Duke Fiscal Years (July 1 – June 30)

Zika Risk Exclusions

	FY16	FY17	FY18	FY19	TOTAL
Zika Risk	2	70	178	186	436
% of Cryopreserved CBUs	0.09%	3.69%	9.20%	10.72%	5.57%

*****Over the past 2 years, ~10% of banked units have been excluded for Zika travel exclusions**

Exclusions due to ID testing

	FY16	FY17	FY18	FY19	Total
Chagas	0	0	2	2	4
HBC	0	0	1	1	2
HCV	2	2	4	0	8
HIV	2	7	1	4	14
HTLV	5	1	4	8	18
Syphilis	3	2	7	1	13
West Nile	0	0	0	1	1
Total	12	12	19	17	60

% Cryopreserved CBUs 0.53% 0.63% 0.98% 0.98% 0.77%

HepB Core

	FY16	FY17	FY18	FY19	TOTAL
HepB Core	22	14	14	7	57
% of Cryopreserved CBUs	0.97%	0.74%	0.72%	0.40%	0.73%

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Zika Risk CBUs by Race

	# CBUs	% of Total Zika CBUs
African American	53	12%
Asian	36	8%
Caucasian	190	44%
Hispanic	90	21%
Multirace	66	15%
Native American	1	0%
	436	100%



Marcus Center for Cellular Cures

Duke University School of Medicine



Zika Risk and HRSA Goals

	Pending Cohort 5 Targets as of July 31, 2019	CBUs Excluded for Zika Risk	% Goals represented by Zika Risk CBUs
African American	356	53	15%
Asian	73	36	49%
Caucasian	718	190	26%
Hispanic	267	90	34%
Multirace	241	66	27%
Native Hawaiian	2	0	0%
	1,657	435	26%

Examples

- Dad was on a cruise, 6 months prior to conception, that docked in Haiti for a few hours. Dad never left the boat.
- Parents took a weekend trip to a resort in Mexico 3 months before conception
- Dad connected on a flight in an airport in Miami 3 months into pregnancy

Recommendations

- ✓ **Obtain detailed travel histories for baby's mother and father**
- ✓ **Test all mothers with Zika NAT as part of DS/DT**
- ✓ **Confirm normal PE (esp lack of microcephaly) on newborn physical examination**
- ✓ **For donors with travel risks:**
 - ✓ Obtain follow-up 1-year post donation and confirm that baby is healthy, has normal development, and has had no significant illnesses in the first year of life that would raise suspicion of Zika infection.
- ✓ **If confirmed, donor is eligible, unit is licensed and NCBI eligible.**

THANKS

?Questions?



Carolinas Cord Blood Bank

A not-for-profit public cord blood bank