

ZIKV IMPACT ON ELIGIBILITY DETERMINATION OF THE HCT/P DONORS-CORD BLOOD(CB)

RODICA M CIUBOTARIU, MICHAL TARNAWSKI, NELA-LUDY DOBRILA, MARIA S ALBANO, ANDROMACHI SCARADAVOU, PABLO RUBINSTEIN
NATIONAL CORD BLOOD PROGRAM, NEW YORK BLOOD CENTER, LIC, NY, UNITED STATES
CP:32



BACKGROUND AND PURPOSE

- Zika virus (ZIKV) infection transmitted to humans by A. Aegypti mosquitos has been linked to central nervous system malformations in fetuses.
- Due to a theoretical risk of ZIKV transmission through HCT/P and a documented transplacental transmission during the first trimester of pregnancy or during delivery, FDA identified ZIKV as a relevant communicable disease and amended its Donor Eligibility Guidelines (FDA “Donor Screening Recommendations to Reduce Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products”, March 2016), and thus all the donors with potential exposure to ZIKV shall be declared ineligible.
- The Purpose of this study was to determine the impact of maternal potential ZIKV exposure on donor eligibility determination for National Cord Blood Program (NCBP) HCT/P donors.

RESULTS AND DISCUSSIONS

- Eligibility was assigned for 1335 clinical grade CBUs collected in all five NCBP collection sites between 3/2016-12/2016.
- 356 CBUs(27% of clinical CBUs) were declared ineligible.
- 278 CBUs (21% of clinical CBUs and 78% of ineligible) had at least one ZIKV related risk factor.
- Note: Since the aim of this study was the analysis of ZIKV impact on donor eligibility, we ranked ZIKV as primary reason; some CBUs had additional risk factors.
- Donor racial distribution among the 278 ZIKV ineligible CBUs was: Caucasian 52%, Asian 9%, Black/AA 20%, and Multi-race 21%, whereas racial distribution of all clinical CBU donors was Caucasian 49%, Asian 15%, Black/AA 20%, and Multi-race 17%, suggesting there is no race correlation for this risk factor, which seems to be highly driven by cultural habits such as family travel.

STUDY DESIGN AND METHODS

- Cord blood units (CBU) collected *ex utero* in all five NCBP collection sites-which qualified as clinical grade-were assessed for eligibility determination when maternal medical history, risk factor information and tests results were in place.
- Donors were declared ineligible for ZIKV reasons as shown in Table

CONCLUSIONS

- Our study indicates that currently the leading risk factor for ineligible CB donors is the maternal potential exposure to ZIKV: 78% of all ineligible CBUs and 21% of all banked CBU in the study period.
- We anticipate the number of such cases to decrease following obstetricians’ provided maternal education and CDC travel warnings.
- Recognizing the importance of ZIKV in public health, as well as its potential transmission via HCT/P products, an FDA approved screening test for HCT/P donors becomes a timely necessity.

TABLE: ZIKV RISK FACTORS AND IMPACT ON DONOR ELIGIBILITY DETERMINATION

Risk Factors	N	% Ineligible of Total CBU	% of Ineligible
A. Mother had*:			
a) Traveled to ZIKV area	227	17	64
b) Residence in ZIKV area	26	2	7
c) Residence in + Travel to ZIKV area	25	2	7
B. Mother had sex with a man who had:			
a) Traveled to ZIKV area	214	16	60
b) Residence in ZIKV area	21	2	6
c) Residence in + Travel to ZIKV area	3	0.2	0.8
C. Mother had A+B	191	14	54

* In the 12 months before delivery

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