CBB Survey 2015 ION-4565

CBB Survey 2015

1. General Information	
Name of CBB	Slovene Cord Blood Bank (ESPOK)
Date CBB Started Collecting Cord Blood Units (month/day/year)	04/08/2005
Number of Public Cord Blood Units	1,064
Planned Number of Public Cord Blood Units Stored in 2015	0
Lists on BMDW	Yes
Affiliated with National Stem Cell Donor Registry	Yes
Registry Affiliation	Slovenia Donor
2. Cord Blood Units in Inventory	
Current Processing Method	Liquid+ red auto
Previous Processing Method	Vapour+ red auto
Year Current Process Method Started	2008
Percent of Units Plasma and RBC Reduced (automated)	95
Percent of Units No Volume Reduction	5
3. Accreditations, Licenses and Certifications	
FACT-Netcord	No
AABB	No
Competent Authority/ National Health Authority	Yes
Name of Competent Authority	Public Agency of the Republic of Slovenia for Medicinal Products and Medical Devices (JAZMP)
Audited by National Stem Cell Registry	Yes
ISO	No
4. Cord Blood Collection	
Current Collection Practice Is the collection In/Ex -Utero or both?	Ex-utero
Current Antiseptic	Alcohol
Collection Bag	Double needle
Agitation during Collection	Manual
5. Conditioning/Transport from Collection Site to CBB	
Secondary Bag Used	Yes
Transport Conditions	Qualified transporter
Transport Conditions	Insulating transport container
Transport Conditions	Passive refrigeration system

Transport Conditions	Electronic temperature probe
Transport Conditions	Ground transport
Temp. for Storage and Transport	Other (lower limit +1-35°C, higher limit +6-30°C)
6. Pre-Processing Evaluation	
Completed Prior to Accepting a CBU	Medical history, collection report, informed consent
Current Threshold for Accepting a CBU	Viability threshold CD34
Method for CD34 Remuneration	ISHAGE guidelines
External Proficiency Testing for QC of FACS Lab	UKNEQAS
Post Processing/ Pre Freeze CD34+ Cell Count	Yes
Time from Collection to Processing	up to 48H
7. Processing and Packaging	
Pre Freeze Processing Methods- Unit in Inventory	No processing
Pre Freeze Processing Methods- Unit in Inventory	SEPAX
Pre Freeze Processing Methods- Current	SEPAX
Additives Currently in Use	No additive
Current Cryopreservation Method	Conventional CRF
Current Cryopreservation Method	Other: Programmed freezer
Current Cryoprotectant Additive	DMSO
Current Cryobag	Single bag (one fraction)
Current Target Cryopreservation Volume (mL)	50.0
Current Packaging for Storage	Overwrap
Current Packaging for Storage	Canister
Current Packaging for Storage	More than one segment
8. Testing	
Extra Material Currently Stored	Cord blood material for DNA extraction
Extra Material Currently Stored	Plasma/cord blood
Extra Material Currently Stored	Maternal DNA
Extra Material Currently Stored	Maternal plasma/serum
Current Post Processing Threshold for Accepting a CBU for Public Use TNC	90
Current Post Processing Threshold for Accepting a CBU for Public Use CD34 (10^6) Single Platform	NA
Current Post Processing Threshold for Accepting a CBU for Public Use CD34 (10^6) Double Platform	0,1
Current Post Processing Threshold for Accepting a CBU for Public Use CFU-GM	1
Current Post Processing Threshold for Accepting a CBU for Public Use CFU	1
Current Post Processing Threshold for Accepting a CBU for Public Use Viability	70
9. Storage	
Type of Storage Container Used	Conventional storage tank vapor phase
Type of Storage Container Used	Conventional tank liquid phase

Monitoring of Storage	Centralized alarm system local
Monitoring of Storage	Centralized system remote monitoring
Monitoring of Storage	LN2 level
Monitoring of Storage	Lid opening
Monitoring of Storage	Temperature monitoring
10. HLA Typing	
Current Level of HLA Typing at Time of Listing HLA-A	HR
Current Level of HLA Typing at Time of Listing HLA-B	HR
Current Level of HLA Typing at Time of Listing HLA-C	HR
Current Level of HLA Typing at Time of Listing HLA-DRB1	HR
Current Level of HLA Typing at Time of Listing HLA-DQB1	
Current Level of HLA Typing at Time of Listing HLA-DPB1	
Accreditation of HLA Lab	EFI accredited lab
Average Turnaround Time for Extended HLA Typing Results in days	7
Attached Segment Used for Confirmatory/ Verification Typing	Yes
Units Listed without Attached Segment and have not been Previously Typed on Attached Segment	No
Percentage of CBUs that have an Attached Segment	90-100%
Confirmatory/ Verification Typing on an Attached Segment is Pre-Release Requirement	Yes
11. Reservation and Cancellation Policies	
What Point is a CBU Reserved for a Patient	Reservation request
Length of Time a CBU can be Reserved in days	30
Reservation Fee	No
Reservation Cancellation Fee in Absence of Shipment Request	No
Can Reservation be Extended	No
Is a Unit Report Provided on a Unit that is Reserved for Another Patient	Yes
Is TC Informed when CBU is Released	Yes
12. Release and Shipment	
Hemoglobinopathy Screening Performed Prior to Release	Yes
Criteria to Ship a CBU Viability and Cell Count	70
Criteria to Ship a CBU HLA Identity Testing	Yes
Current Packaging for Shipment to TC	Metal canister
Current Packaging for Shipment to TC	One attached segment
Current Packaging for Shipment to TC	Overwrap
Time Between Shipment Request and Sending CBU	4 days-1 week

Fee for Shipment Cancellation	Yes
Dry Shippers Validated to Maintain Temperature of at least -150 for 48 hours Beyond Expected Arrival	Yes
Electronic Temperature Data Logger on All Dry Shippers	Yes
Who Selects Transport Company	Requesting transplant centre
Shape of Transport Container	Cubic
13. Adverse Events Reporting	
Who are S(P)EARS Reported To Competent Authority	Yes

14. Pictures of cord blood units in the inventory

15. Infectious Disease Marker (IDM) CURRENTLY performed.

Holiday Calendar

Team Calendars