

“Workgroup Cord Blood Thawing and Washing Charge/Accomplishments/Next Steps”

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Work Group Participants+

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Background

- Decades focus has been on establishing cord blood banks
- FDA licensure now in place
- Important laboratory steps in cord blood banking
 - Preparation for cryopreservation
 - Cryopreservation
 - Thaw at transplant center
- Preparation for cryopreservation processing methods varied
- Banks provide thawing and preparation instruction to transplant centers

Background (Contd)

- Many transplant centers may not be adequately prepared for cord blood processing and infusion
- Thawing, washing, and transfusion procedures vary among transplant centers
- Some/many transplant center staff not formally trained in cord blood thaw/wash procedures
- Transplant centers use bank thaw/wash recommendations inconsistently
- Reporting of infusion-related adverse events is incomplete and inconsistent



Actions Suggested by Workgroup

- Determine clinical effect of different pre-cryopreservation procedures
- Reduce number of different thawing protocols
- Create a training program for cord blood thawing/washing
- Require transplant centers to validate thawing procedure in use
- Formalize guidelines for single and double cord blood infusion
- Ask accrediting agencies to create relevant standards for cord blood processing at transplant centers
- Require transplant centers to train on thawing/washing techniques

Actions Suggested by Workgroup (cont.)

- Publish white paper on cord blood thawing and infusion
- Work with NMDP, CIBMTR, and BMTCTN to strengthen thawing/washing processes and training
- Request AABB and FACT to enhance inspection related to thawing/washing and transfusion
- Consider randomized trial comparing thawing only versus washing
- Develop recommendations for transplant center activities
- Urge/support development of enhanced adverse event reporting system

Clinical Effect of Cord Blood Processing

- Principal Investigator: Karen Ballen
- Study Origin: CIBMTR
- Working Committee: Graft sources and manipulation
- Study #: GS05-01
- Title: Effect of cord blood processing & thawing techniques on transplant outcomes after single myeloablative umbilical cord blood transplantation
- Short Title: CB processing & thawing techniques on MA CB HCT outcomes
- Current Status: Manuscript preparation
- Current Stage: Preliminary results

Wash-Related Data And Experience

- Determine extent to which transplant laboratories follow cord bank processing recommendations
 - Unknown
- Determine whether current accreditation processes have this information
 - The do not
- Determine whether cord blood post-thaw processing methods impact clinical outcome
- Publish White Paper on cord blood processing procedures
 - Akel S, Regan D, Petz L, McCullough J, et al. Current thawing and infusion practice of cryopreserved cord blood: the impact on graft quality, recipient safety, and transplantation outcomes. Transfusion (in press, 3/14)

NMDP/CIBMTR/BMTCTN

Proposed Activities

- Decrease thaw methods
 - No progress; not sure if NMDP perceives need
- Carry out training program for transplant center labs
 - Session at last NMDP annual meeting
 - Other progress unknown
- Require validation of processing methods at transplant center labs
 - Progress unknown
- Promulgate/promote/modify transplant center lab activities
 - Progress unknown
- Define standard process for transfusing 2 cord blood units
 - In FACT standards

Transplant Center Laboratory-Related Activities

- Advance communication between cord blood bank
- Receipt and inspection of unit
- Storage of the Unit
- Preparation of transplant center lab before transplant
- Quality control of the process and critical values
- Infusion of the cord blood unit and nursing care of the patient

Resolution from previous Council meeting:

The work group proposes that the Council recommend to HRSA that the following descriptions of activities that occur at the transplant center laboratory be used by the cord blood coordinating center as a blueprint to develop additional training, technical assistance, or operating policies.

FACT/AABB Accreditation Process

- Create processing standards
 - See next slide
- Require training
 - Not implemented

Transplant Center Processing Issues

- FACT
 - Circular of Info must be provided.
 - Provide Practice CB unit if center not familiar with process.
 - Practice unit clearly labelled “for nonclinical use”.
 - Because there have been documented adverse effects related to the administration of CB units containing RBC the FACT Standards (the non CB standards) require dilution and/or washing of cellular therapy products that have not been red cell reduced. This practice is also recommended for products that have been red cell reduced.
 - In the case of double CB transplants, the Clinical Program must wait to administer the second unit until it is determined that the first unit was administered safely with no adverse events.
- AABB
 - Silent on processing at Transplant Center.

Adverse Event Reporting

- System developed and implemented by NMDP
- Reports at previous Council meetings indicate
 - System in place and functioning
 - Urge NMDP to continue to stress importance to participating transplant centers
 - Suggest continuing reports at future Council meetings

Conclusion

- Pre Cryopreservation clinical impact
 - CIBMTR manuscript
- Wash – No Wash; Procedure impact
 - Review article
- Transplant Center Labs
 - Determine whether problem exists
 - Expand and harmonize standards, if feasible
 - Develop and require training programs
 - Develop more coordinated approach by NMDP, FACT, AABB, CIBMTR, and BMTCTN