



Unrelated Products Received From Outside the NDMP Structure

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FDA Liaison Meeting
January 4, 2007

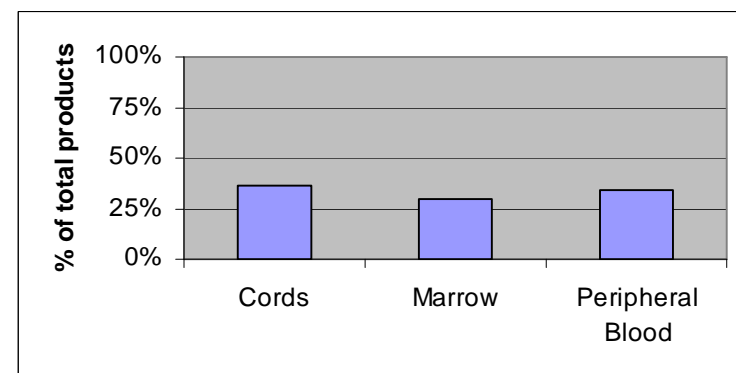
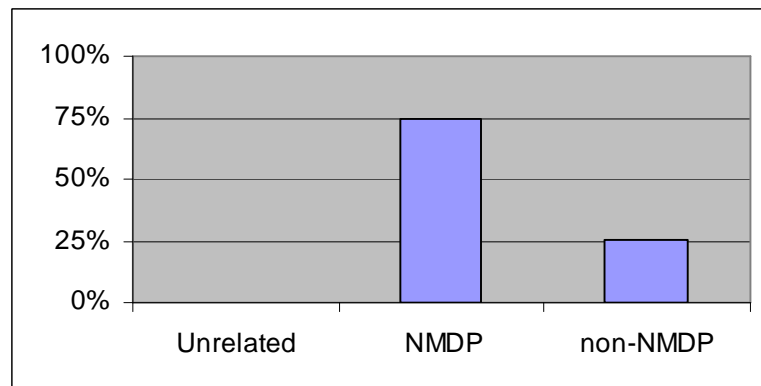
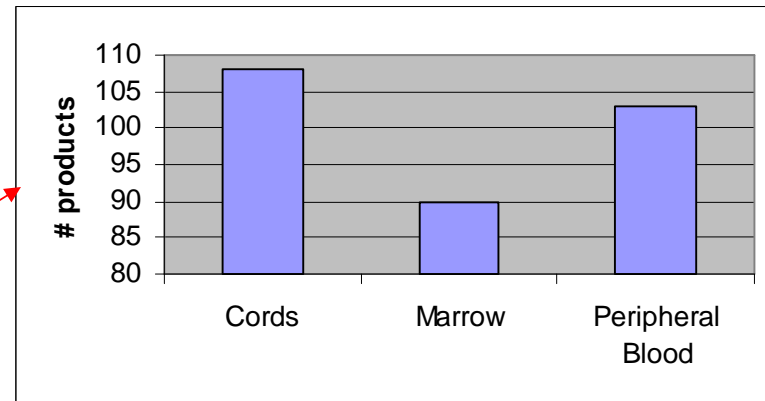
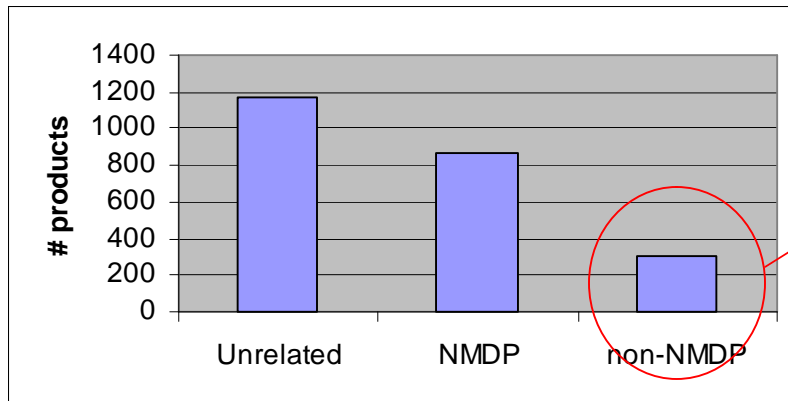


Goals

- n Snapshot of the current situation with unrelated transplants
 - Talked to Directors from 9 centers
 - n Included the Top 5 Centers based on NMDP numbers
 - Breakdown of numbers of products
 - Rough numbers
 - n Point out trends
- n Subset analysis of three of the centers

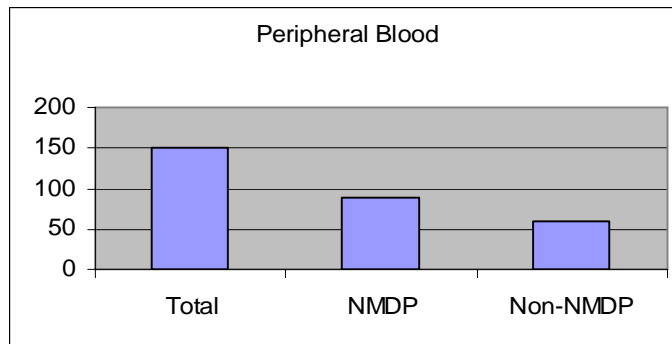
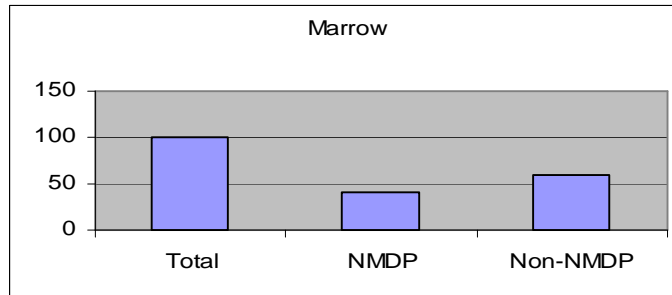
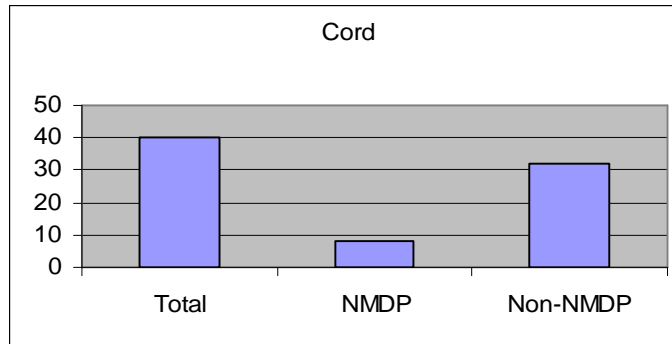
Transplant Centers

n= 9



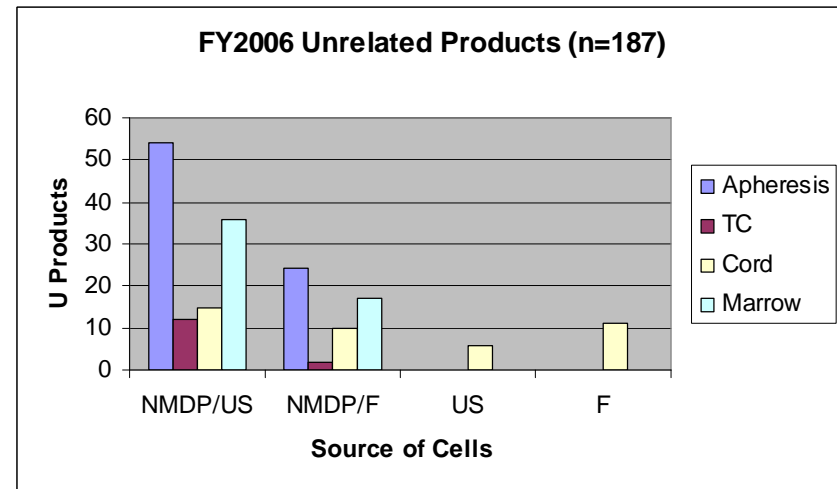
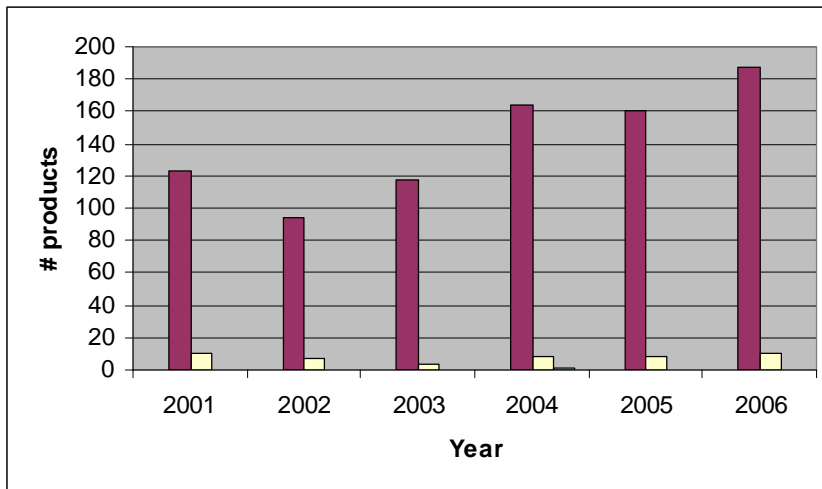
Large Unrelated Transplant Center

n=290 Unrelated Products



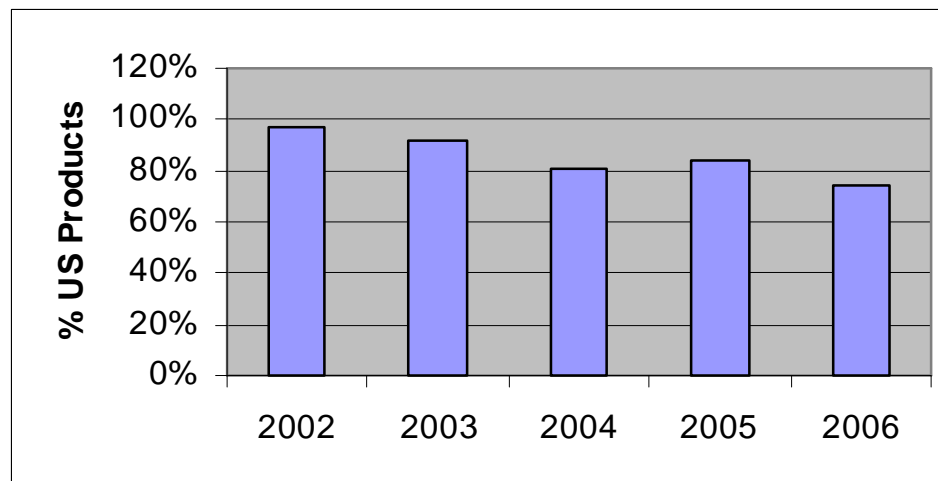
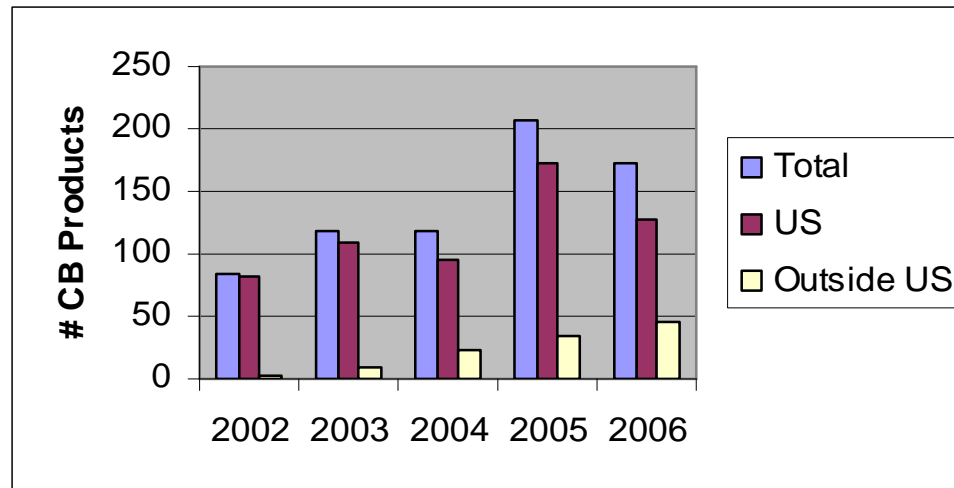
Unrelated Transplant Center #2

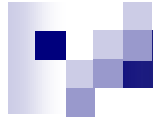
n=187 Unrelated Products



CB Transplant Center

2006, n = 172





How do transplant centers
qualify collection centers?



Qualification of Vendor

- n Wide variation from center to center
 - .. Variation between types of products
- n None of these are licensed products



Audit Form

RECEIPT OF HPCs/LYMPHOCYTES FROM NON-NMDP SUPPLIERS

Patient Name _____ History # _____
Requesting Physician _____ Expected Date of Infusion _____
Shipping Facility _____
Shipping Facilities Address _____
Phone # and Fax # _____
Contact Name and Phone # _____

Additional information required from shipping facility:

Collection and processing facilities' FDA registration number _____
Collection and processing facilities' accreditation information (FACT, AABB, other) _____

Copies needed:

Summary of the product collection
Summary of donor eligibility determination (allogeneic donors only)
Infectious disease marker results (within appropriate time frame from collection date)
Name of laboratory performing infectious disease tests and that they are FDA registered.

Copy or summary of processing information to include:

- Type of processing
- Sterility
- Flow Analysis
- Any additional quality control of product

The collection and processing facility is approved as a supplier.

Quality Assurance: _____ Date: _____



Qualification of Vendor

n Qualification

- .. Audit forms
- .. Check for FDA registration
- .. Check for AABB/FACT accreditation
- .. Instructions of expectations
- .. Require paperwork beforehand to get English translation
- .. Infectious disease testing kits
- .. Note- they would use the product even if these things were not accomplished



Qualification of Vendor

n No Qualification

- NMDP is first choice but if not available
- Medical Decision
- HLA is top priority and/or cell numbers for CB
- Monitor engraftment
- Urgent Medical need



Points to consider

- n Do we need a better data set?
 - CIBMTR data and then follow up survey
- n Should there be minimum requirements for qualification of collection centers?
 - White paper?
 - Guidance document from FDA?
 - Everything must come through NMDP?
- n Sliding scale based on clinical indication or basic minimum requirements
- n FDA approved ID testing kits?
 - n HPC-A – everyone is following guidelines
 - n HPC-C – accepting what collection/storage facility has