Cord Blood Advisory Group: Organization and Highlights
(from November 2013 meeting)

Presented to the AABB Center for Cellular Therapies Cord Blood subsection by
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NMDP Cord Blood Advisory Group

• Formed early in NMDP involvement in cord blood facilitation
• Includes representatives from:
  – Cord Blood Banks – medical directors and staff
  – Transplant physicians
  – Research
  – Laboratory
  – Regulatory
  – Government agencies – HRSA
  – NMDP staff
NMDP Cord Blood Advisory Group

• Accomplishments
  – Set inventory criteria – collection, processing, testing, cell counts
  – Set suitability criteria – maternal, family, and infant
  – Accreditation by either AABB of NetCord/FACT as a membership criteria
  – Collaboration with CIBMTR for improved reporting to the banks
  – Inter-bank proficiency program
NMDP Cord Blood Advisory Group

- Three subgroups
  - Research
    - Potency
    - Proficiency Testing
  - Collections
    - Best Practices
    - Recruitment Materials / Donor Education
  - Quality Standards
    - Review of adverse events and product complaints
    - Inventory requirements
    - Data forms – MRQ, FMHQ
- Cord Blood Data Working Group
NMDP Cord Blood Advisory Group

• Subgroups meet quarterly
  – Teleconference

• Meet twice per year
  – In person
  – June associated with Cord Blood Symposium
  – November/December – Minneapolis

  – Agenda includes:
    • Reports from subgroups
    • Update from HRSA
    • Update from NMDP
    • Current topics / Broader range topics
      – Cord blood usage, pricing, licensure, strategy
NMDP Cord Blood Advisory Group

• Highlights from last meeting
  – HRSA update
    • CW Bill Young transplant program shows growth – donor and cord blood
      – Over 11.2 million donors on registry – 3 million racial/ethnic minority, 400,000 donors added in 2013
      – Almost 284,000 CBUS on registry – over 40% minority
      – 7.7% increase in number of tx
  – NMDP update
    • See decline in cord blood shipments and transplants, both imports and exports
    • Inventory growth continuing – larger units (TNC) being added as well as selected by TCs
    • Growth in haplo transplants

Have we saturated use until new indications
Cord Blood Use Trend Worldwide (including Japan)

Cord Unit Use

- 2008: 3522
- 2009: 3813
- 2010: 4087
- 2011: 4574
- 2012: 4288
Trends in Haplo Use – CIBMTR Data

• Growth in use of haploidentical transplants in US:

<table>
<thead>
<tr>
<th></th>
<th>2009</th>
<th>2012</th>
<th>Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caucasian</td>
<td>123</td>
<td>218</td>
<td>77%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>17</td>
<td>55</td>
<td>224%</td>
</tr>
<tr>
<td>Afr Amer</td>
<td>36</td>
<td>100</td>
<td>178%</td>
</tr>
<tr>
<td>Total</td>
<td>176</td>
<td>373</td>
<td>120%</td>
</tr>
</tbody>
</table>

• Haplo as a percentage of alternative donor (unrelated+cord+haplo) transplants:

<table>
<thead>
<tr>
<th></th>
<th>2009</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caucasian</td>
<td>4%</td>
<td>5%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>6%</td>
<td>14%</td>
</tr>
<tr>
<td>Afr- Amer</td>
<td>18%</td>
<td>28%</td>
</tr>
</tbody>
</table>
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- NMDP update continued
  - Pricing discussion, pricing models, cost issues related to banking, selective banking, education of payors
  - Cord blood transplant focus and education
  - Ways to decrease costs
    - Centralized high resolution recruitment typing
    - Group purchasing
    - Reimbursement for patients on clinical trials
- Subgroup reports
  - Research - Retrospective CFU study
  - Cord Blood data working group – changes to outcomes reports, standardization for info provided to FDA
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• Highlights of last meeting cont.
  – TC Release Criteria Survey
    • NetCord/FACT survey
    • Info on general testing performed at TC as well as requirements for identity testing
    • Raw data available and will be analyzed for next meeting
    • Actions to take/recommendations to make as result of survey
  – EmTrax/Operations Updates
    • Review of updates since releases of application
    • Demonstration of proposed query functionality
    • Need for TC education on ISBT ID numbering system
    • Review of quarterly reports of patient searches
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• Highlights of last meeting cont.
  – Collection related Topics
    • Best practices survey
    • Remote collections project summary
    • Possibility of standardized national kit
  – Licensure
    • 5 banks currently licensed, 2 have had their one year post inspection
    • Not every unit licensed at a bank that holds a license
    • Effect on reimbursement through NCBI program
  – New Business
    • Consent process – two step?
    • Blood transfusion/IV fluids and hemodilution