Label Design
Task Group

ISCT
Berlin 2006

Cellular Therapy Coding &
Labeling Advisory Group
Members

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Task

• To come up with draft labels for common cell therapy products

• Present these for review and discussion
Challenges

- Variety of Product types
- Variety of container types
- Variety of container sizes
- Variety of storage conditions
- Amount of information per label
Approach

• Choose 3 common label sizes
  – Standard Transfer pack label
  – Small vial label (1.5 x 0.75 inches)
  – Bioarchive label (cord blood banking)

• Generate samples for common products
Transfer Pack Label
MUD Apheresis

<table>
<thead>
<tr>
<th>Collection Facility</th>
<th>Year</th>
<th>Collection Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>W1234 06 123456 01</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Collection Date: 0006031515
30 JAN 2006 15:15 GMT

FOR USE BY INTENDED RECIPIENT ONLY
Matched Unrelated Donor
Donor #: 123654987

Validation Counts and other Laboratory Testing Information

Recipient:
John Q. Patient
ID#: 123456789
Date of Birth: 31 DEC 1984
Hospital Name
City, Province, Country

HPC, APHERESIS

Approx ___ mL in approx ___ mL ACD
DO NOT IRRADIATE
DO NOT USE LEUKOREDUCTION FILTER
Stors at 1 to 6 C
Processing Laboratory Elsewhere, Worldwide

Expiration Date and Time
0006031515
31 JAN 2006 15:15 GMT

Rh Positive
5100
Transfer Pack Label
MUD Apheresis

Donor Information

Blood Group

Required Warnings

Donor Information

Test results etc.
Transfer Pack Label
MUD Apheresis

Collection Information

Collection Center ID
Collection Date & Time
Required Warnings

Donor Information

Blood Group
If applicable
Required Warnings
Donor Information
Test results etc.

Recipient:
Name: John Q Patient
ID#: 123456789
Date of Birth: 31 DEC 1984
Hospital Name
City, Province, Country

Test results etc.
Transfer Pack Label
MUD Apheresis

Collection Information

Collection Center ID
Collection Date & Time
Required Warnings

Donor Information

Blood Group
If applicable
Required Warnings
Donor Information
Test results etc.

Product Information

Product Proper Name
Volume & additives
Required Warnings
Storage conditions
Processing Lab ID

Example of a label with:
- Collection Center ID: W1234 06 123456 8 1
- Collection Date: 30 JAN 2006 15:15 GMT
- Blood Group: O Rh Positive
- Product Proper Name: HPC, APHERESIS
- Storage conditions: Store at 1 to 6 C
- Processing Laboratory Elsewhere, Worldwide

Recipient:
- John Q Patient
- ID#: 123456789
- Date of Birth: 31 DEC 1984
- Hospital Name
- City, Province, Country
<table>
<thead>
<tr>
<th>Transfer Pack Label</th>
<th>MUD Apheresis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Collection Information</strong></td>
<td><strong>Donor Information</strong></td>
</tr>
<tr>
<td>Collection Center ID</td>
<td>Blood Group</td>
</tr>
<tr>
<td>Collection Date &amp; Time</td>
<td>Required Warnings</td>
</tr>
<tr>
<td>Required Warnings</td>
<td>Donor Information</td>
</tr>
<tr>
<td>Product Proper Name</td>
<td>Test results etc.</td>
</tr>
<tr>
<td>Volume &amp; additives</td>
<td>Recipient Information</td>
</tr>
<tr>
<td>Required Warnings</td>
<td>Expiration date &amp; time</td>
</tr>
<tr>
<td>Storage conditions</td>
<td>If applicable</td>
</tr>
<tr>
<td>Processing Lab ID</td>
<td>Recipient Information Name</td>
</tr>
<tr>
<td></td>
<td>#</td>
</tr>
<tr>
<td></td>
<td>DOB</td>
</tr>
<tr>
<td></td>
<td>Hospital Name &amp; Location</td>
</tr>
</tbody>
</table>

**Recipient Information**
- Name: John Q. Patient
- ID#: 123456789
- Date of Birth: 31 Dec 1984
- Hospital Name: Elsewhere, Worldwide
- City, Province, Country

**Product Information**
- Proper Name: HPC, APHERESIS
- Volume & additives: Apox ___ mL in approx ___ mL ACD
- Storage conditions: DO NOT IRRADIATE
- Processing Laboratory: Elsewhere, Worldwide

**Donor Information**
- Blood Group: O Rh Positive
- Expiration Date and Time: 31 Jan 2006 15:15 GMT
- Required Warnings: Matched Unrelated Donor
- Donor ID: 123456789
- Validation Counts and other Laboratory Testing Information

**Required Warnings**
- Properly Identify Intended Recipient. May transmit infectious agents.
- FOR USE BY INTENDED RECIPIENT ONLY
- Matched Unrelated Donor
- Donor ID: 123456789

**Test results etc.**
- Matched Unrelated Donor
- Donor ID: 123456789
- Validation Counts and other Laboratory Testing Information
Autologous Donor

Donor Information

Blood Group
If applicable

Required Warnings
& Autologous Designation

Test results etc.
Vial Label

Component #: C1234567

Therapeutic Cells, T-cells

Recipient: SMITH, John

TCH MRN #: 98705324

Information required on Partial Label

Unique identifier of product

Proper name of product

Recipient name & Identifier
2-Dimensional Barcodes

- Allow encryption of a lot of data
- Not readable by many linear barcode readers
- Not FDA approved
- Multiple formats
- Dual format barcode readers ~$1,000
- Expert panel in place to make recommendations
BioArchive™ Cord Blood Labels

As used by MD Anderson Cancer Center

1.75”

2”

Courtesy of Thermogenesis
NMDP Operational Issues/Questions

• Current NMDP donor identification code is not specific to the donation.
  – Adoption of new numbering system must link with donor registry number.

• Will all collection facilities (including bone marrow) have the capability to generate labels?

• Centers need to have continued capability of including a local donor/product ID on label

• Will there be mandatory fields of entry on the label that will prevent printing of the label?
Future Tasks

• Feedback on draft label designs
  • Individuals
  • Cell Processing Centers
  • Registries
  • Regulatory Agencies
  • Professional organizations
  • Any others

Send to apgee@txccc.org
Future Tasks

- Label modifications
- Use of new terminology on labels
- Resolution of 2-D label issues
  - Input from expert panel
  - Feedback from centers
  - Acceptance by regulatory agencies