Implementing ISBT128 Labeling for a Multisite BMT Program

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ISBT 128 Labeling

Objectives:

- Implementing ISBT 128 labeling for a multi-site BMT program
- Describe and review the labeling system design process, implementation and validation
- Discuss current issues and challenges
ISBT 128 Labeling

Introduction:

- The Leukemia/Bone Marrow Transplant (BMT) Program of British Columbia (BC) is located in the city of Vancouver.

- Our Program operates 5 main areas:
  - Apheresis Unit
  - Clinical Cell Therapy Laboratory
  - Inpatient Unit
  - Outpatient Daycare Unit
  - Four Outreach Clinics

Find out about us at: http://leukemiabmtprogram.com
In 2010, Apheresis Program collected/processed 205 products:

- **ALLO: 53**
  - 49 HPC, Apheresis
  - 4 TC, Apheresis

- **AUTO: 152**

In 2010, Clinical Cell Therapy Laboratory processed 172 products:

- **ALLO: 19**
  - 2 HPC, Cord Blood, thawed/diluted
  - 9 HPC, Apheresis, cryopreserved
  - 8 TC, Apheresis, cryopreserved

- **AUTO: 153**
  - 1 Bone Marrow, Buffy coat enriched, Plasma Reduced
  - 152 HPC, Apheresis, cryopreserved
BC Cancer Research Centre
ISBT 128 Labeling

- Timeline
- Project coordinators
- Where do we start!
- Equipment
- Label Design
- Donation Identification Number
- Product Codes
Timeline

- Exposed to ISBT 128 global labeling system in the mid 2000ths via ISCT and CBMTG conferences.
- Medical Director required automated labels – ISBT 128 provided a global standard for terminology, labeling and identification. Registered with ICCBBA in June 2007
- Weekly meetings were initiated Jan 2008
- Implemented ISBT 128 labeling standards in November 2008
This project was spearheaded by myself and Chao-Yong Lee who is the software programmer familiar with the different databases from each site.

We divided the tasks into two categories- one would look at the requirements for ISBT 128 standards and the other would look at software issues.
Where do we start!

- Reviewed information available on the ICCBBA website
  - ISBT Standard Technical Specification
  - ISBT Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions

  47:1312-1318
  ISBT 128 Implementation Plan for Cellular Therapy Products
  Paul Ashford, Pat Distler, Adrian Gee, Alan Lankester, Stella Larsson, Irene Feller, Kathy Loper, Derwood Pamphilon, Leigh Poston, Fran Rabe, Ineke Slaper-Cortenbach, Zbigniew Szczepiorkowski, and Phyllis Warkentin
ISBT 128 Labeling

Weekly Meetings

- A flow chart was established to better understand the possible variables and site requirements.
- Review existing database from the Apheresis Unit (in house) and Cell Therapy Laboratory (third party database) to determine if they could integrate and support ISBT 128
- Determine what product codes were required
- ICCBBA was continually contacted throughout the planning process (they continue to assist us)

ANALYSIS of DATA FLOW and STORAGE
Equipment Requirements

- Printers: After looking at a number of different options we decided on the Zebra S4M model.
  
  It is affordable, simple to use heavy duty label printer with a 8" media roll capacity.

  The Cell Therapy Laboratory has two printers, one for single labels and one for our cryopreserved product labels. The Apheresis unit has one printer as well as the BMT coordinators.

- Scanners: Once we established that we were going to use 2-D bar codes that intern dictated what kind of scanner was required.
Printer & Scanner

Zebra S4M label Printer

Model DS3478SF
Design labels using ZebraDesigner Pro

Product label for collection facility:

Label size: 4”x4”
Label content: specified by ICCBBA
Data source: From Apheresis database
We have been buying our labels from Shamrock which is one of the suppliers listed on the ICCBBA website.

![Label example](image-url)
Labels for Cryopreserved Products

- Labels for cryopreserved products were a little more challenging.
- We determined that we required bag labels and vial labels and we would rather have one 4X4 label sheet provide both configurations.
- We use Baxter cryocyte bags and the label size is the same for all bag sizes. (new bags are validated)
- We came up with the following 7 part label design
Design labels using ZebraDesigner Pro

- **Product label for Processing Facility:**
  - Label size: 4”x4”
  - Label is divided into 3 sections:
    - 5 vial labels
    - 1 tie-tag label
    - 1 insert label

---

**Product Bag**
Cryocyte Bag

- Bag Label
- Tie tag
- Vial label
Reverse of the Cryocyte Bag
Donation Identification Number

- Facility Identification number (FIN) e.g. C0020

- Donation identification number: We use the product collection date and sequential number: YYMMDDNN

- Flag (00=default)

Example of DIN: C00201105210200
Product Codes

Product codes include Class, Modifier and Attributes:

1. Class
2. Modifier
3. Attributes:
   - Anticoagulant
   - Storage temperature
   - Intended use group
   - Manipulation
   - Cryoprotectant
   - 3rd Party component
   - Other additives
   - Genetically modified
## Converting Product Codes

- Generating an excel file for product codes to allow sorting product codes by product specification:

<table>
<thead>
<tr>
<th>CODE</th>
<th>MODIFIER</th>
<th>CLASS</th>
<th>ANTI-COAG</th>
<th>STORETEMP</th>
<th>MANIPULATION</th>
<th>CRYO</th>
<th>3rdParty</th>
<th>Additive</th>
<th>ForUse</th>
<th>GenMod</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1185</td>
<td></td>
<td>CONCURRENT PLASMA,</td>
<td>Citrate</td>
<td>rt</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1186</td>
<td></td>
<td>CONCURRENT PLASMA,</td>
<td>Citrate</td>
<td>rt</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1157</td>
<td></td>
<td>CONCURRENT PLASMA,</td>
<td>Citrate+Hep</td>
<td>rt</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1179</td>
<td></td>
<td>CONCURRENT PLASMA,</td>
<td>Citrate+Hep</td>
<td>rt</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1128</td>
<td></td>
<td>HPC, APHERESIS</td>
<td>Citrate</td>
<td>rt</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1129</td>
<td></td>
<td>HPC, APHERESIS</td>
<td>Citrate</td>
<td>rt</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1134</td>
<td></td>
<td>HPC, APHERESIS</td>
<td>Citrate</td>
<td>re/f</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1135</td>
<td></td>
<td>HPC, APHERESIS</td>
<td>Citrate</td>
<td>rt</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1144</td>
<td></td>
<td>HPC, APHERESIS</td>
<td>Citrate</td>
<td>re/f</td>
<td>CD34 enriched</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1146</td>
<td></td>
<td>HPC, APHERESIS</td>
<td>Citrate</td>
<td>rt</td>
<td>CD8 reduced</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1147</td>
<td></td>
<td>HPC, APHERESIS</td>
<td>Citrate</td>
<td>re/f</td>
<td>CD8 reduced</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1148</td>
<td></td>
<td>HPC, APHERESIS</td>
<td>Citrate</td>
<td>re/f</td>
<td>CD133 enriched</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1149</td>
<td></td>
<td>HPC, APHERESIS</td>
<td>Citrate</td>
<td>rt</td>
<td>CD133 enriched</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1156</td>
<td></td>
<td>HPC, APHERESIS</td>
<td>Citrate</td>
<td>rt</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>
Type of Donation
(intended use)

- 1 autologous eg. S1475100
- X autologous, biohazard eg. S1475X00
- 2 directed recipient only eg. S1475200
- 3 directed recipient, biohazard eg. S1475300
- E directed recipient, medical exception eg. S1475E00
- 4 designated collection eg. S1475400
- 6 designated collection, biohazard eg. S1475600
How does this work?
Transferring data from one database to another

Donor/recipient information retrieval:

<table>
<thead>
<tr>
<th>Identification</th>
<th>Admissions</th>
<th>Lymph Screen</th>
<th>Plt Transfusions/CBCs</th>
<th>BMTs</th>
<th>CSU Appt.</th>
<th>IDMs</th>
<th>HPC Counts</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Full Name</strong></td>
<td>SMITH, John</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Birth</strong></td>
<td>1990-01-01</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>VGH MRN</strong></td>
<td>111222333</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PHN</strong></td>
<td>123456789</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Diagnosis</strong></td>
<td>Normal Donor</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td>M</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>BCCA#</strong></td>
<td>10012345</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>BMT ID#</strong></td>
<td>123456</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CSU ID#</strong></td>
<td>S0123456</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**HLA Typing**

- HLA-A
- HLA-B
- anti-HLA
### Product information retrieval:

<table>
<thead>
<tr>
<th>Identification</th>
<th>Admissions</th>
<th>Lymph Screen</th>
<th>Plt Transfusions/CBCs</th>
<th>BMTs</th>
<th>CSU Appt.</th>
<th>IDM</th>
<th>HPC Counts</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BM Type</strong></td>
<td>ALLO HPC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Donor</strong></td>
<td>123456</td>
<td>CSU S012345678</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SMITH, JOHN</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Birth</strong></td>
<td>1990-01-01</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Patient</strong></td>
<td>112233</td>
<td>CSU P019920101</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SMITH, JANE</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Birth</strong></td>
<td>1992-01-01</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>50.0 Kg</td>
<td>Primed GCSF</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>** Prod. ID#/Date**</td>
<td>2010021701</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>WBC x10^9/L</strong></td>
<td>125.8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total WBC x10^9</strong></td>
<td>440.3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Platelet x10^11</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>RBC Vol (ml)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ACD-A (ml)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total Vol (ml)</strong></td>
<td>350</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>CD34+%</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total CD34+ x10^6</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cryopreserved</strong></td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Click Product ID# field to select the product before clicking Label button.*
The labeling system automatically fills in data from databases on the screen:

<table>
<thead>
<tr>
<th>Donation ID#</th>
<th>Facility</th>
<th>Product ID#</th>
<th>Flag</th>
<th>ABO/RhD</th>
<th>Biohazard</th>
<th>RBC Compatible</th>
<th>Collect Date/Time</th>
<th>Process Date/Time</th>
<th>Expiry Date/Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>C002010</td>
<td>C0020</td>
<td>1002170</td>
<td>00</td>
<td>5800</td>
<td>NO</td>
<td>YES</td>
<td>2010-02</td>
<td>2010-02</td>
<td></td>
</tr>
</tbody>
</table>

**Product Information**

<table>
<thead>
<tr>
<th>Code</th>
<th>Modifier</th>
<th>Collection</th>
<th>Anticoag</th>
<th>Storage Temp</th>
<th>Manipulation</th>
<th>Cryoprotectant</th>
<th>Additive</th>
<th>3rd Party</th>
</tr>
</thead>
<tbody>
<tr>
<td>S050</td>
<td>SMITH, JOHN</td>
<td>111222333</td>
<td>1990-01-01</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1165</td>
<td>SMITH, JANE</td>
<td>1992-01-01</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1179</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1156</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>S1129</td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>S1135</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Donor Information**

- **ID#:** S05091010
- **Name:** SMITH, JOHN
- **Birth:** 1990-01-01

**Recipient Information**

- **PHN:** 111222333
- **Name:** SMITH, JANE
- **Birth:** 1992-01-01

**Product Details:**
- Code: S1128
- Modifier: HPC, Apheresis
- Collection: Citrate
- Anticoag: Citrate
- Storage Temp: in 2 to 8°C
- Manipulation: No
- Cryoprotectant: No
- Additive: YES

- Code: S1148
- Modifier: HPC, Apheresis
- Collection: Citrate
- Anticoag: Citrate
- Storage Temp: in 2 to 8°C
- Manipulation: CD133 enriched
- Cryoprotectant: Yes
- Additive: No

- Code: S1475200
- Modifier: <=-120°C
- Collection: 10% DMSO
- Anticoag: Plasma reduced
- Storage Temp: 2 to 8°C
- Manipulation: 5800 A
- Cryoprotectant: NO
- Additive: YES

- Code: S1155
- Modifier: HPC, Apheresis
- Collection: Citrate
- Anticoag: Citrate
- Storage Temp: in 2 to 8°C
- Manipulation: T/B-cell reduced
- Cryoprotectant: No
- Additive: Yes

**Buttons:**
- Create New Donation ID#
- Print Label + Transfer Data
- Infuse this Product
- Transfer Data Only
- Exit
The labeling system automatically fills in data from databases to the labeling program ZebraDesigner Pro:
Bag Divisions

Apheresis collection
S1128100

HPC-A, autologous, mobilized, citrate, refg

CCT Lab
S1475100

HPC-A, autologous, citrate,
Plasma reduced, 10% DMSO,
Plasmalyte A, Cryopreserved,
≤ 120°C

S14751A0

S14751B0
Labeling System Features

- User friendly with dropdown selection lists
- Provide reference for product code listings
- Minimal data entry required: Pre-fill data with donor, recipient and product information from existing databases
- Expiry times are automatically calculated
- Flexible labeling design to allow modification
- Automatic data transfer from the labeling system to the database
Implementation

Staff training:

- Prior to system implementation, we provided training sessions for
  - Cell Therapy Lab staff
  - Apheresis Program staff
  - BMT coordinators
  - BMT data coordinators

- Created an online User’s Guide for quick reference
- Developed SOP for the labeling system
Validation

- Data Transfer log file:
  - Record the process of data transferring for auditing

- Audit tables in database:
  - Record changes to the database tables

- Weekly data transfer review:
  - Check for any errors or missing data

- Labeling system log file:
  - Record any problems/changes made to the labeling system
Validation

- Print all combinations of Labels
  - Verify label and enables tracking of label version
  - Blank labels available for all combinations for down times
  - One label example completed for all blank labels
Current issues and challenges

- **New product codes**
  - The time required to receive new product codes for new attributes can be longer than expected

- **Understand and select an appropriate product code**
  - It is not a trivial task to determine a product code for a given product
    - Example: Plasma added as additives vs. as manipulation “diluted”
    - Example: Heparin as anticoagulant vs. as additives
Current Issues and Challenges

- **Products from other facilities before ISBT128 implementation:**
  - Current system requires the donation identification number is defined by the collection date (YYMMDD) and a sequential number (01-89 for internal products and 90-99 for external products)
  - Should we create a donation identification number for the product or use the originating product number?

- **Unrelated donors**
  - Keeping the FIN confidential, currently we are using the registry (OneMatch) which does not have a FIN number. Therefore we use our FIN number in the database, but it does not print on the label ie*****11052190.
Stand Alone

- Equipment, labels, software are supplied
Acknowledgement

Our project would not be possible without tremendous help and continuing support from:

**Erwin Cabana**, Information Standards Specialist, ICCBBA
Helped with proper formatting for label design

**Pat Distler**, MS, MT(ASCP)SBB, Technical Director, ICCBBA
Helped us understand and clarify product codes
Acknowledgement

Chao-Yong Lee

Clinical Cell Therapy Laboratory