Label Design
Label Requirements for HCT/Ps

- Meet labeling principles
- Suitable for
  - Range of container sizes
  - Range of storage temperatures/conditions
  - Sequential addition of information
- Eye and machine readable critical information
Types of Label

- ‘Standard’ Blood Pack Label – 100mm x 100mm
- Partial Labels – 48mm x 76mm and 96mm x 38mm
- Cryopreservation Labels
- Vial labels
ISBT 128
Label Design

- Design based on that used for blood products
- Information based on four quadrant design
- Information may be accumulated sequentially
ISBT 128 Labels
Base Label 4” x 4” (& 3” x 3”)

- Label applied by container manufacturer
- Contains bar codes for:
  - Manufacturer identity
  - Catalogue number
  - Lot number
Standard Label

- Based on the "four quadrant" model
Upper Left Quadrant

Donation Identification Number and collection facility or registry information

Collection date, if needed (may or may not be bar coded)

Warning Statements (nationally defined)
W1256  07  123456  K

- Five character Facility or Registry Identification Number
- Year
- Serial number
- Flags (number or icon)
- Keyboard entry check character
Facility or Registry Identification Number

- Assigned by ICCBBA to either a registry or a facility

  - If assigned to a registry, registry must be able to link Donation Identification Number to the collection facility and ICCBBA database will show only the name of the Registry

  - If assigned to a facility, facility name and location may be found in ICCBBA database
If Facility or Registry Identification Number

- Database available to all registered users
- Look-up program available to all at www.iccbba.org
NMDP

- Will not use a registry Facility Identification Number
- Each facility should use its own Facility Identification Number
- Do not put facility name and location in the text
W1256  07  123456  ☐ K

- Five character Facility or Registry Identification Number
- Year
- Serial number
- Flags (number or icon)
- Keyboard entry check character
W1256  07  123456  K

- Five character Facility or Registry Identification Number
- Year
- Serial number
- Flags (number or icon)
- Keyboard entry check character
- Five character Facility or Registry Identification Number
- Year
- Serial number
- Flags (Indicates where number or icon was scanned e.g. tube or product)
- Keyboard entry check character
W1256 07 123456 ☑ K

- Five character Facility or Registry Identification Number
- Year
- Serial number
- Flags (number or icon)
- Keyboard entry check character – checks data entered from keyboard (ISO 7064 Mod 37-2)
Lower Left Quadrant

- Internationally standardized Product Code assigned by ICCBBA
- Name/description of product (translated to local language)
- Product specific warnings
- Processing facility, if applicable
RED BLOOD CELLS
CPD, 450ml, refg
Res Leucocytes < 1 x 10^6
Plts & Cryo reduced
Blood Group/Type (if known)

Biohazard symbol (if applicable). Also encoded in bar code

Donation type (Auto, directed). Also encoded in bar code.

Product test results (if applicable—nationally defined)
Upper Right Quadrant

Donation type and Donor ID, Text Only (if applicable). May be ISBT 128 number or local number.
## Lower Right Quadrant

<table>
<thead>
<tr>
<th>Expiration Date if applicable (may or may not be bar coded)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recipient Information (depending on donation type)</td>
</tr>
</tbody>
</table>

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

**Expiration Date and Time:**
- 31 JAN 2007 10:15
- (31 JAN 2007 15:15 GMT)
Example

- Donor Leukocytes
  - At collection
  - At distribution – fresh cells
  - Cryopreserved DLI
<table>
<thead>
<tr>
<th>Label: DLI Label, Collection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Collection Center or Registry</strong>: Anywhere, Worldwide</td>
</tr>
<tr>
<td><strong>Collection Date/Time</strong>: 22 JAN 2007 13:59</td>
</tr>
<tr>
<td><strong>Laboratory Testing Information</strong>:</td>
</tr>
<tr>
<td><strong>Expiration Date/Time</strong>: 24 JAN 2007 13:59</td>
</tr>
<tr>
<td><strong>Recipient</strong>: John Q Patient</td>
</tr>
<tr>
<td><strong>Processing Laboratory</strong>: Elsewhere, Worldwide</td>
</tr>
<tr>
<td><strong>Label</strong>: RhD Positive</td>
</tr>
<tr>
<td><strong>Barcode</strong>: W0000 07 123456 3 D</td>
</tr>
</tbody>
</table>

**Details**: TC, Apheresis
- **Store at**: 1°C to 10°C
- **DO NOT IRRADIATE**
- **DO NOT USE LEUKOREDUCTION FILTER**

*Note: The image contains a barcode and additional information that is not transcribed here.*
DLI, Distributed (Fresh)

Collection Center or Registry
Anywhere, Worldwide

Collection Date/Time
22 JAN 2007 13:59
(22 JAN 2007 18:59 GMT)

Laboratory Testing Information
Additional Laboratory Testing Information

Recipient:
John Q Patient
ID#: 123456789
Hospital Name
City, Province, Country

TC-T Cells
Third party donor product(s) present
Additional additive(s) present
See attached information for details
Approx. 10 ml in Citrate
Store at 1°C to 10°C
DO NOT IRRADIATE
DO NOT USE LEUKOREDUCTION FILTER

Processing Laboratory
Elsewhere, Worldwide
DLI, Cryopreserved

See attached labeling for further information.

Intended Recipient:
Wilson, Jeffrey
MR#: 07061234B

Partial Label  Expiry Date: 14 JUN 2018
Partial Labels

- Limited Space – has to fit pouch
- Two Sided
- Bar Coded Donation Number and Product Code
- Additional Human Readable
  - Product Description
  - Collection Date
  - Expiry Date
  - Collection Facility
  - Patient Identification
Cryopreservation Label (1)

- Special Label, (central hole)
- Very Limited Space
- Bar Coded Donation Number
- Additional Human Readable
  - Product Description
  - Expiry Date
  - Patient Identification

![Image of cryopreservation label with barcodes and additional information]
2-Dimensional Codes

- Newer technology
- Requires imaging scanner
- Higher density
- One code, several items of information
- Some modification to software systems
- Uses existing ISBT 128 data structures
Size Comparison

Code 128

Data Matrix
Cryopreservation Label (2)

- Special Label, (central hole)
- Bar Coded
  - Donation Number
  - Product Code
  - Expiry Date
- Additional Human Readable
  - Product Description
  - Expiry Date
  - Patient Identification
Vial Label (1)

- Designed for 1.5 – 2ml capacity vials
- Very limited space
- Information presented as for Cryo labels
Next Stage

- Each country may make limited changes to the international design for use in their country
- These are made by National Consensus Groups
- US Consensus group met on 10/24/07 to propose the US labels
Next Step

- Approval for US changes from the CTLAG
- Discussion of Issues with CTLAG
- No implementation date
- Professional standards groups will adopt ISBT 128 nomenclature and label design
Thank you
ISBT 128:
More Than Labeling

Leigh Sims Poston, BS, MT(ASCP)
Information Elements

• Standard terminology and definitions
• Reference tables
  - Consistent product codes
• Data structures
• Delivery mechanisms
• Labeling
ISBT 128 Information Hierarchy

1. Definitions
2. Reference Tables
3. Data Structures
4. Delivery Mechanisms
5. Labeling
Information Elements

• **Standard terminology and definitions**
  • Ensure understanding throughout CT community
  • Built and managed by international consensus to ensure consistency and level of detail
  • Adaptable to new products

• **Reference tables**
  – Consistent product codes

• **Data structures**

• **Delivery mechanisms**

• **Labeling**
Information Elements

- Standard terminology and definitions
- Reference tables
  - Provide means of mapping definitions to codes
  - Ensure consistent interpretation
  - Flexible, additions permitted, managed
    - Consistent product codes
- Data structures
- Delivery mechanisms
- Labeling
Information Elements

- Standard terminology and definitions
- Reference tables
  - Consistent product codes
    - Product codes assigned by ICCBBA, Inc.
    - New code built by specifying a combination of defined characteristics that becomes incorporated into the product database table, ensuring that product will be accurately identified worldwide
- Data structures
- Delivery mechanisms
- Labeling
Information Elements

• Standard terminology and definitions
• Reference tables
  – Consistent product codes
• Data structures
  • Technical definitions for data transfer
  • Allow independent systems to communicate
  • Developed and maintained to meet needs
• Delivery mechanisms
• Labeling
Terminology Standard for Cellular Therapy Products

- The Terminology Standard is essentially a dictionary of terms for cellular therapy products.

- Each term has an associated definition.
Terminology Standard

• Constructed by international consensus to ensure global consistency in use and understanding

• Published after public review and comment:

Terminology Standard

• Provides basis for assignment of product descriptions within the database

• Highly flexible and comprehensive

• Defines New Products – by combining pieces of information from the dictionary to clearly describe the product.
  – Unique product description assigned a product code incorporated into data base.
Terminology Standard

• Due to growth / changes within the field of CT many of the initial coding terms defined in the 1990s were revised or replaced.

• ISBT 128 Standard: Cellular Product Coding Transition, version 1.2.0, July 2007. (www.iccbba.org)
Terminology Structure

- Product description database uses three concepts to describe products
  - Class
  - Modifier
  - Attribute
Terminology Structure

• **CLASS**: broad description of the product
  
  • The product as collected – intent or cell source or after manufacturing.
  
  • At any time in its history, a product has one & only one class; this designation may change over the course of processing, manipulation, or manufacturing.
Terminology Structure:
CT Definitions

**CLASSES:**

Product as collected: intent and cell source:

- HPC, APHERESIS
- HPC, CORD BLOOD
- HPC, MARROW
- HPC, WHOLE BLOOD
- CONCURRENT PLASMA, APHERESIS

-- OR --

Product after manufacturing: (variable purity)

- TC-T CELLS
- TC-CTL
- TC-T REG CELLS
- TC-DC
- TC- NK CELLS
- TC-TUMOR DERIVED
- TC-MSC
- TC- APC
- TC-INV
Terminology Structure

- **MODIFIER**: applied to class to provide the next step in categorization of the product
MODIFIERS:

- Mobilized: Applies to cells that have been obtained from a donor treated with an agent to increase the concentration of the target cell population(s) [to be used only for TC, Apheresis or bone marrow]

- Non-mobilized: ...not treated... [HPC, Apheresis or HPC, WB]

- Cryopreserved

- Pooled, single donor: ...multiple collections...

- Thawed, washed

- Washed: ...non-cryopreserved product...

- Thawed

Intent is to use modifiers when the action would result in relabeling of the product because it occurred in a laboratory, not at the bedside.
Terminology Structure

• **ATTRIBUTE**: additional characteristic(s) to uniquely identify the product
  
  • **CORE CONDITIONS**: mandatory attributes
  
  • **GROUPS & VARIABLES**: optional attributes
Terminology Structure

• **ATTRIBUTE**: **CORE CONDITIONS**
  • Mandatory; one of each must be explicitly selected
  • Convey three types of information:
    • Anticoagulant
    • Volume
    • Storage Temperature
Terminology Structure: CT Definitions

Attributes – **Core Conditions**:

- **Anticoagulant**
  - Citrate
  - Heparin
  - Citrate + Heparin
  - NS
  - None
- **Volume**
  - XX
- **Storage temperature**
  - Refrig
  - RT
  - $\leq -18^\circ\text{C}$
  - $\leq -80^\circ\text{C}$
  - $\leq -120^\circ\text{C}$
  - $\leq -150^\circ\text{C}$
  - $\text{N}_2$ liquid [immersed]

- **only anticoagulant in any solution**
- **sole method of anticoagulation**
- **combine in any concentration**
- **anticoagulant not specified in coding**
- **no anticoagulant**
- **volume not specified in coding**
- **(1-10°C; ± nationally specified narrower)**
- **(range nationally specified)**
Terminology Structure

• **ATTRIBUTE**: GROUPS & VARIABLES

  • Optional; have default value if not assigned

  • Groups are general categories to describe detailed applicable characteristics; only one variable within a group may be selected
    • Intended use
    • Cryoprotectant
    • Manipulation
    • Preparation – 3rd party blood component
    • Preparation – other additive
    • Genetically modified
Terminology Structure: CT Definitions

Attributes – **GROUPS & VARIABLES**:

- **GROUP: Intended Use**
  - For Administration  [DEFAULT]
  - Not for administration
  - For further processing

- **GROUP: Cryoprotectant**
  - No cryoprotectant  [DEFAULT]
  - 6% HES + 5% DMSO
  - 10% DMSO
  - 5% DMSO
  - DMSO reduced
Terminology Structure: CT Definitions

Attributes – **GROUPS & VARIABLES**:

**GROUP: Preparation: 3rd party blood component**
- NO [DEFAULT]
- YES

**GROUP: Preparation: other additive**
- NO [DEFAULT]
- YES

**GROUP: Genetically modified**
- NO [DEFAULT]
- YES
Product Example

• CLASS HPC, APHERESIS

• MODIFIER Cryopreserved

• ATTRIBUTES: Core Conditions
  • Anticoagulant Citrate
  • Collection Volume NS
  • Storage Temperature $\leq -150^\circ$C

• ATTRIBUTES: Groups & Variables
  • Intended Use For administration
  • Cryoprotectant 10% DMSO
  • Manipulation Plasma reduced
  • 3rd party blood component No
  • Other Additive Yes
  • Genetically modified No
Product Code Data Structure

- Product Code is 8 characters long:
  \[ S1221X00 \] [not actual code]
- First 5 characters describe all of the terminology and definitions previously discussed
  - First character defines type of product:
    \[ S = \text{cellular therapy product} \]
  - Next 4 characters \([1221]\) define class, modifiers, attributes - core conditions, groups and variables. Specific combinations are maintained in the Reference Tables
- Sixth character \([\text{eg, X}]\) specifies the type of donation / collection / or intended use \([\text{autologous, directed, URD}]\)
- Characters 7 & 8 encode information about divisions of products; up to 26 divisions

Example Label: Cellular Therapy Product

- Product
Acknowledgements:

Special thanks to:

• Phyllis Warkentin
• Pat Distler
• Paul Ashford

for providing many of the slides used in this presentation today and

• The CT Coding and Labeling Advisory Group for all of their work to develop the standard and their future work in reviewing proposed additions.
Implementation of ISBT 128 in a Cellular Therapy Facility

Cellular Therapy Coding and Labeling Advisory Group (CTCLAG)
Getting Started

- Before developing a plan for implementation, you must have support for and a commitment to ISBT 128.
- Involve key personnel (Medical Director, Laboratory manager(s), Quality Assurance, Information Technology manager(s), other key roles) in the decision process.
Appoint a Project Manager

Select someone knowledgeable about

- Cellular Therapy Laboratory Operations / Procedures
- Available Computer System
- Cellular Therapy Labeling Applications

And who is resourceful, persistent, persuasive, and committed to the project
Resources—Gather information

- www.iccbba.org
  - An Introduction to ISBT 128
  - ISBT 128 for Cellular Therapy
  - ISBT 128 Standard Technical Specification
  - ISBT 128 Standard Bounded Lists and Definitions
  - ISBT Standard Product Code Structure and Labeling (Cellular Therapy)
  - ISBT 128 Standard Cellular Therapy Product Coding Transition

- www.aabb.org
- Your software vendor
- Label vendors
Early Phase: Review Educational Materials
Determine Level of Involvement

- ICCBBA Registration (all facilities that will apply ISBT 128 bar codes to CT product labels are required to register)
- Manual system (use pre-printed labels, handwritten information)
- Limited automation (will use pre-printed labels and will scan bar codes)
- Full electronic (read and print bar coded labels)
- Electronic data transfer (use of this feature provides quick efficient transfer of product information between organizations)
Costs

Budgeting Process Considerations:
- Software ? (Purchase or Upgrade)
- Bar Code Scanners ? (Linear or Imaging)
- Labels ? (Pre-printed or On-demand)
- New Forms (Printing, etc.)
- Labor
Don’t Forget: Obtain Executive Management Support

- The project will involve commitment of human and financial resources
- If anyone in executive management was not a part of the decision-making process to implement ISBT 128, now is the time to involve them
Communication: Inform Associated Laboratories / End Users

It’s not just a different label!

- Identify other involved departments / laboratories
  - Testing Services
  - Nursing / Infusion Staff
  - Billing Staff
- Bring key associated staff into planning process
Prepare “The Plan”
Let the Writing / Revising Begin:

- Write: Implementation Plan
- Revise / Update: Quality Plan
- Write: Validation Plan / SOPs (software, equipment, processes)
- Write / Update: Training Plan

✓ Remember: Follow Change Control Policy
Implementation Plan

- Essentials for writing a useful implementation plan
  - Understand the product codes
  - Understand label design
  - Determine equipment, software and supply needs
Understand Product Codes

- ISBT 128 Standard Bounded Lists and Definitions
- Cellular Therapy Product Coding Transition
- ISBT 128 Standard Product Code Structure and Labeling (Cellular Therapy)
- Access database for Product Code Descriptions
Product Code Descriptions

- Rules Based
- Built by combining Classes, Modifiers, and Attributes
- Select from existing codes or request new ones
Compile List of Product Codes

- Populate computer tables
- Set up billing mechanisms
- If collection/processing facility, share with your customers
<table>
<thead>
<tr>
<th>Code</th>
<th>English</th>
<th>Swedish</th>
</tr>
</thead>
<tbody>
<tr>
<td>E5395</td>
<td>POOLED PLATELETS</td>
<td>PASII/XX/20-24C</td>
</tr>
</tbody>
</table>
Understand Label Design

- ISBT 128 Standard Technical Specification
- ISBT 128 Standard Product Code Structure and Labeling
- Regulatory Documents for national requirements
Determine Equipment, Software and Supply Needs

- Scanners
  - Linear Imaging
- Printers
- Software
- Labels

www.iccbba.org for vendors licensed with ICCBBA
## 2-D vs. Linear Bar Codes

<table>
<thead>
<tr>
<th>Data Matrix</th>
<th>Code 128</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Barcode Image]</td>
<td>Donation ID number</td>
</tr>
<tr>
<td>![Barcode Image]</td>
<td>ABO/Rh</td>
</tr>
<tr>
<td>![Barcode Image]</td>
<td>Product Code</td>
</tr>
<tr>
<td>![Barcode Image]</td>
<td>Expiration Date/Time</td>
</tr>
<tr>
<td>![Barcode Image]</td>
<td>Special Testing results</td>
</tr>
</tbody>
</table>

Copyright ICCBBA, Inc
Validation

- All new equipment, software, supplies (including labels), and processes must be validated.

- Validations should be performed according to the facility’s policies and procedures, in conjunction with any applicable standards and regulations and vendor recommendations.
Validation

- Software (Purchase)
  - Supplier Qualification

- Software (Purchase or In-house)
  - Validation Plan
    - Include installation and functionality testing
    - Parallel operation

- Labels (Pre-printed, On-demand, Combination)
  - Label material, adhesive, and bar codes
  - Valid and invalid labels that may be used for validation purposes may be found on the ICCBBA website.
Execution Phase

But wait, “I am not quite ready”.
Plan for the Transition Phase

- If you receive ISBT 128 labeled products before you’ve implemented
  - Will your computer be able to scan labels?
  - Update SOPs to be able to deal with products received

- If you implement first
  - Share label examples with facilities that will receive your products in advance of shipping the first product
Execution Phase

- Purchase Equipment
- Write Equipment Validations
- Perform Equipment Validations
- Write SOPs
- Perform SOP Validations
Education and Training

- Develop training materials
- Identify who will need training
  - Laboratory / Technical staff
  - Nursing and Medical staff
  - Information Technology
  - Billing personnel
- Train staff
Audit Quality System Procedures

- Quality Plan
- Emergency Response Plan
- Contingency Plan
- Computer down/Back-up Plans
Go Live – Implementation Day
Assess Progress

- Areas / Systems that functioned well
- Areas / Systems that did not function well
- How were problems addressed / handled
- Identify any errors and/or accidents
Resources:
Seek Assistance When Needed

- ICCBBA (iccbba@iccbba.org)
- Colleagues who have implemented *ISBT 128*
- Sponsoring Organizations (ISCT, AABB)
Good Luck!
Cellular Therapy Coding and Labeling Advisory Group


Advisory Group will continue to advise re: new product codes, definitions
Educate, promote use of ISBT128 Standard
Ensure continued consistency with professional standards