ISBT 128

International Information Standard for Transfusion and Transplantation
Outline

- The Objective
- The Information Environment
- ISBT 128
- Role of ICCBBA, Inc
- Basics of Labeling using ISBT 128
The Objective

- To provide a standard information environment that:
  - supports the open movement of cellular therapy products around the world in such a way that critical information is rapidly, accurately and unambiguously communicated;
  - satisfies regulatory requirements for traceability and retention of information.
The Information Environment

- Standard Definitions
- Reference Tables
- Data Structures
- Delivery Mechanisms
- Labeling
Information Hierarchy

- Definitions
- Reference Tables
- Data Structures
- Delivery Mechanisms
- Labeling
The Basic Elements

- Standard Definitions
  - Ensure common understanding across the community
  - Built and managed by international consensus of experts

- Reference Tables
- Data Structures
- Delivery Mechanisms
- Labeling
The Basic Elements

- **Standard Definitions**
- **Reference Tables**
  - Provide means of mapping definitions to codes
  - Ensure consistent interpretation
  - Flexible but managed
- **Data Structures**
- **Delivery Mechanisms**
- **Labeling**
<table>
<thead>
<tr>
<th>ABO and Rh(D) Blood Groups</th>
<th>Default: Intended Use Not Specified</th>
<th>Directed (Dedicated/Designated) Collection Use Only</th>
<th>For Emergency Use Only</th>
<th>Directed (Dedicated/Designated) Collection/Biohazardous</th>
</tr>
</thead>
<tbody>
<tr>
<td>O Rh(D) negative</td>
<td>95</td>
<td>91</td>
<td>92</td>
<td>93</td>
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<tr>
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<td>02</td>
<td>03</td>
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<td>59</td>
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<td>13</td>
<td>14</td>
<td>15</td>
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<tr>
<td>B Rh(D) Positive</td>
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<td>69</td>
<td>70</td>
<td>71</td>
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<td>24</td>
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<td>26</td>
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<tr>
<td>AB Rh(D) positive</td>
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<td>81</td>
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<td>C2</td>
<td>C3</td>
<td>C4</td>
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<td>D2</td>
<td>D3</td>
<td>D4</td>
</tr>
<tr>
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<td>E2</td>
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<td>E4</td>
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<td>G2</td>
<td>G3</td>
<td>G4</td>
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<tr>
<td>Bombay, Rh(D) positive</td>
<td>H6</td>
<td>H2</td>
<td>H3</td>
<td>H4</td>
</tr>
</tbody>
</table>
The Basic Elements

- Standard Definitions
- Reference Tables
- Data Structures
  - Technical definitions for data transfer
  - Allow independent systems to communicate
  - Developed and maintained to meet community needs
- Delivery Mechanisms
- Labeling
Data Structure

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Group O, Rh negative
The Basic Elements

- Standard Definitions
- Reference Tables
- Data Structures
- Delivery Mechanisms
  - Means of delivering information
  - Linear bar coding, radio frequency tags (RFID), Reduced Space Symbology (RSS) codes, 2-dimensional bar codes
  - Need the underlying elements to provide the required functionality
- Labeling
The Basic Elements

- Standard Definitions
- Reference Tables
- Data Structures
- Delivery Mechanisms
- Labeling
  - Defines means of providing information in the right place and format
  - Ensures consistency between electronic and eye-readable information
What is ISBT 128?

- **ISBT 128** is an information standard for transfusion and transplantation
- Developed for transfusion by International Society of Blood Transfusion (ISBT) in 1994
- Being extended to further support Cellular Therapy
- Defines:
  - Reference Tables
  - Data Structures
  - Delivery Mechanism
  - Labelling Guidance
Key Elements

- Unique donation numbering system (global)
- Standard structures and formats for information
- International product list, definitions and codes
- Standard data structures for other key information (status information, expiry, HLA profiles etc.)
- Mechanism for development and maintenance of the standard
Role of ICCBBA, Inc

- Not-for-profit organization
- development and maintenance of the standard
- assignment of new codes
- technical support
- educational material
- promotion
ISBT 128 Labels

- Blood
- Tissue
- HPCs
If space permits…

102 mm x 102 mm (4” x 4”)

102 mm x 102 mm (4” x 4”)
Location of bar codes

Donation Identification Number

Collection Date

Product Code

ABO/Rh

Expiration Date

Special Testing
Full size blood label (US)

Accurate Blood Center
Anywhere, USA
FDA Registration Number 123456

Properly Identify Intended Recipient
See Circular of Information for indications, contraindications, cautions and methods of infusion.
May transmit infectious agents
Rx Only
VOLUNTEER DONOR

RED BLOOD CELLS
ADENINE-SALINE (AS-1) ADDED

From 450 mL CPD Whole Blood
Store at 1 to 6 C

US License Number 123

Exp & Date 31 JAN 2006

Rh POSITIVE

Expiry Date 0060312359

Negative for antibodies to CMV

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isbt 128
More than Identification