Introduction to the ISBT 128 Labelling Standard for Blood Components

Hospital IT Perspective

What is ISBT 128?

“An international standard for the transfer of information associated with tissue transplantation, cellular therapy and blood transfusion.

It provides for a globally unique donation numbering system, internationally standardized product definitions and standard data structures for bar coding and electronic data interchange.”
ISBT 128 Technology Standard

- Much more than a new label layout
- Provides standard information and layout for blood component labels
- Defines data structure for information appearing on labels
- Defines data identifiers for bar codes used in blood component labelling & data transfer
- Defines technical details for the bar code
- Technical Specifications document available on ICCBBA website
ISBT 128 Implementation

- Canadian Blood Services plans to implement ISBT 128 by May 2009
- Will require changes to Canadian Blood Services blood management system (PROGESA)
- Many hospitals may also be required to update their systems
- Will require changes to SOPs, forms and labels
- Implementation timelines announced April 9, 2008 to allow hospitals adequate notice for successful implementation

ISBT 128 Data Structures and Identifiers
ISBT 128 Data Structures

- Data structures define the way information is presented in ISBT 128.
- Data structure can be incorporated into many information delivery systems e.g. bar codes, electronic messages, RFID tags
- Donation Number and Product Code are just two of many ISBT 128 data structures
- When ISBT 128 data structure appears in bar code format the data characters are printed in eye readable format immediately beneath the bar code

ISBT 128 Data Structures

- The data structures and identifiers for the ISBT 128 Donation Number, Product Codes and Blood Groups are summarized in this presentation
- Refer to the current version of the *ISBT 128 Standard Technical Specification* at ICCBBA.org for a complete description of all the ISBT 128 data structures.
### ISBT 128 Data Identifiers

- Data identifiers define the type of information the bar code contains (e.g. Product Code, ABO/Rh Blood Group)
- Each bar code on a blood product will begin with 2 data identifier characters (except Donation Number)
- The first character will always be “=” or “&”. By international agreement, these characters specify an ISBT 128 data structure
- Reduces error since data cannot be entered into an incorrect field
Data Identifiers for Major Bar Codes

= Donation Number
=% Blood Group (ABO/Rh)
=< Product Code
=* Collection Date
=> Expiration Date
>&> Expiration Date & Time
=\ Special Testing: Red Cell Antigen
&( Special Testing: General

Donation Number

ISBT 128 Data Structure 001
Donation Number Data Structure

= apppyynnnnnnnff

= Data identifier
a Country Code
pppp Facility Code
yy Year of Collection
nnnnnn Serial Number
ff Flag Character (NOT part of Donation Number)

ISBT 128 Donation Number

C0500 07 123456

• 13 Digit Donation Number
  – Facility identification code (global)
  – Year indicator (won’t repeat for 100 years)
  – Sequential number (999,999/facility/year)
• Additional elements – not part of DN
  – Flag characters
  – Manual entry check character
ISBT 128 Donation Number

- Donation Number data structure provides unique identification of donation worldwide for 100 years.
- Comprised of 13 data characters.
- Included in the data structure are 2 flag characters and a Keyboard Entry Check Character. These are **NOT** part of the Donation Number.

Donation Number – Flag Characters

- Flag characters are **NOT** part of the Donation Number.
- Are used for process control.
- Will **NOT** be the same on component label as on label applied at collection or what is printed on packing slips.
- Are encoded in the bar code and printed on labels and reports.
Keyboard Entry Check Character

- Keyboard entry into computer system should be strongly discouraged.
- When keyboard entry is necessary, computer software should be designed to recognize manual entry and require entry of Check Character for verification of data entered.
- Check character required for manual entry of long numbers (e.g., donation number and red cell antigen testing)
- Not in the bar code because it’s meant to check KEYBOARD entry
- May want to record in manually written records

ISBT 128 Product Codes and Definitions

ISBT 128 Data Structure 003
ISBT 128 Product Codes & Definitions

8 digit product code data structure includes donation type and allows for definition of additional information

- 5 digit product code which defines
  - Core conditions – e.g. anticoagulant, volume, storage conditions
  - Component Class - e.g. Red Blood Cells, Platelets
  - Modifiers – e.g. washed, thawed
  - Attributes – e.g. irradiated, residual white count, low platelet count

- 3 digits define donation type and divisions/splits

Product Code Database maintained by ICCBBA. All products distributed nationally/internationally must have a standard ISBT 128 product code.

Product Code Data Structure

=αoooootds

αoooo  product code
 t  donation type (e.g. Volunteer, Directed)
 d  divisions A0, B0,
 s  second level divisions Ba, Bb, Bc
Product Code Structure

1st Character
- Indicates Type of Donation
  - E & F: Blood
  - S: HPC (Stem cells)
  - T: Tissue
  - A-D reserved for internal or national use; not defined internationally

E0150V00

Product Code Structure

2nd Through 5th Characters
- Identifies product
- Sequentially assigned--unstructured

E0150100
RED BLOOD CELLS/CPD/from 450 mL whole blood/refrig
Type of Donation

6th Character

- Sixth character identifies donation type
  - E0150V00
  - V = Volunteer Donor
  - 1 = Autologous Use Only
  - 2 = Directed Use Only
  - X = Autologous Biohazard

Divisions/Splits

- E0150V00 (Original product)
  - RED BLOOD CELLS/CPD/from 450 mL whole blood/refrig

- E0150VA0 (Divided from original – e.g. pediatric)
  - RED BLOOD CELLS/CPD/from 450 mL whole blood/refrig/Divided (closed system)

- E0150VAa (Divided from first level division (e.g. syringe))
  - RED BLOOD CELLS/CPD/from 450 mL whole blood/refrig/Divided (closed system)
Product Codes – Codabar vs ISBT 128

- No one to one relationship between Codabar & ISBT 128. Example - CPD Whole Blood:

<table>
<thead>
<tr>
<th>Codabar Product Code</th>
<th>ISBT 128 Product Codes include:</th>
</tr>
</thead>
<tbody>
<tr>
<td>00150</td>
<td>Whole Blood</td>
</tr>
<tr>
<td></td>
<td>Whole Blood</td>
</tr>
<tr>
<td></td>
<td>Whole Blood</td>
</tr>
<tr>
<td></td>
<td>Whole Blood</td>
</tr>
</tbody>
</table>

Example of ISBT 128 Product Code

- Component Class: Red Blood Cells
- Modifier: None
- Core Conditions
  - Anticoagulant: CPDA-1
  - original volume: 450 ml
  - storage conditions: refrigerated
- Attribute: Irradiated

ISBT PRODUCT CODE = E0206
Blood Groups

- Indicates the blood groups (ABO and Rh) or a product
- *Optionally*, may display information indicating
  - Donation type (e.g. Autologous, Directed)
  - Status of donation or collection (e.g. Biohazard, Research Use)
- *Optionally*, may encode information for C, c, E, e, K or Miltenberger phenotypes
Blood Groups Data Structure

=%%ggree

= Data identifier

gg ABO & Rh blood group and type of donation or collection information

r Optional. If used provides Rh, Kell phenotype

e Reserved for future use. Value always set to 0 (zero)

ISBT 128 Standard Label
ISBT 128 Standard Label

- ISBT 128 blood product label is divided into four quadrants
- Regardless of site of collection globally, the bar codes should be placed in same relative positions on product label
- The ISBT 128 Standard defines the placement of the following bar codes:
  - Donation Identification Number
  - ABO/Rh Blood Group
  - Product Code
  - Collection Date
  - Special Testing
- The Canadian Blood Services label design is not finalized and the label will not be exactly as shown in the following diagrams

Standard ISBT 128 End Label Format

Unique Donation Number & Static Text
- 13 digit unique Donation Number (plus flag & manual check characters)
- Blood centre name, address, licence number
- Static legal text

Product Code & Description
- Includes donation type (e.g. autologous, directed)
- Includes divisions (e.g. for pediatric use)
- Includes modifier and attribute information (e.g. washed, irradiated)
Standard ISBT 128 End Label Format

Blood Group
- More prominent
- May indicate intended use
- May indicate Rh, Kell phenotypes

Expiry Date
- Time also shown if other than midnight

Special Testing/ Characteristics (Optional)
- Red Cell Phenotype
- CMV status
- Special information, e.g. antibodies present
- In eye readable and, optionally, bar code format

Extended ISBT 128 Label

- Canadian Blood Services plans to use an extended ISBT 128 label for a transition period to allow hospital systems time to become ISBT 128 compliant
- Duration of transition period has not yet been determined
- Extended portion of label has critical information (Donation Number, Product Code, Blood Group, Facility Code, Expiration) in Codabar format
- Similar format to that implemented by Héma-Québec (refer to CL #2007-24)
ISBT 128 Impact on Hospitals

Impact on Hospitals

Things to consider:

- Project planning and communication
- Work instruction and form revision
- Training of Transfusion Service and Clinical Staff
  - Anyone who handles blood components need training to the changes to the label
- Software preparation & validation
  - Version upgrade may be required
- Hardware requirements – bar code scanners, printers
- Impact on other systems
  - Medical Records, report generating systems
- Registration with ICCBBA
  - Information available at www.iccbba.org
Communication is Key!

- Communication is key to a successful ISBT 128 Implementation
- Anyone who handles blood components or enters/records donation information is potentially impacted
  - Lab staff
  - Systems administrators
  - Logistics staff
  - Nursing staff
  - Physicians
  - Patient records office
  - Hospital education office
  - Senior management
  - Outside agencies

Canadian Blood Services Communications Tools

- Customer Letters
  - CL #2008-06 issued to provide Canadian Blood Services planned implementation date
  - Additional letters will be issued when significant events are planned
- Consultation with Hospital Liaison Specialists
- Presentations
**Canadian Blood Services**

**Communications Tools**

- Internet
  - Information and links to be posted on transfusionmedicine.ca
  - Sample Implementation Readiness Checklist
  - Information Powerpoint presentations
  - Timelines
  - Sample labels
  - Feedback tool for questions – isbt128@blood.ca
  - Database of frequently asked questions

**Canadian Blood Services**

**Implementation Support**

Support will be provided including:

- Adequate and timely information and updates on implementation timelines/plans
- Detailed information on label configuration
- Sample labels
- Product codes
- Facility codes
- Other information required for successful implementation
For more information on ISBT 128 implementation at Canadian Blood Services:
www.transfusionmedicine.ca