Implementing ISBT-128

Beryl Laird
The Blood Center
New Orleans, La.
History of ISBT

• International Society of Blood Transfusion (ISBT):
  – Formed a Working Party on Automation and Data Processing
    • Selected Code 128 for blood labeling (early 90’s)
History of ISBT

- Working Party became International Council on Commonality in Blood Banking (ICCBBA)
  - Charges
    - Introduce ISBT-128
    - Maintain the code internationally
    - Manage registration of facilities
    - Provide information for implementation
History of ISBT

- In 1997 AABB introduced ISBT in 18th Edition of Standards
- In 2000 the FDA recognized ISBT-128 as a standard for uniform labeling
ISBT-128 Timelines

• AABB has stated that:
  – facilities must have a written implementation plan to convert to ISBT 128 by November 1, 2006
  – Facilities must implement ISBT 128 by May 1, 2008
What Are the Benefits of ISBT 128 over Codabar?

- International
- Language independent
- Provides a standard layout
- Capable of encoding an expanded data file in the label
What Are the Benefits of ISBT 128 over Codabar?

• Better accuracy
  – Codabar can have reproducible barcode misreads
  – ISBT-128 has
    • check digit built into the barcode
    • 3 self-checking features/characters
What Are the Benefits of ISBT 128 over Codabar?

• Better traceability – Unit ID includes
  – Facility identification
  – Year of donation
  – Donation sequence number
• Allows concantination
Current Codabar Labeling

Collection Date: 4-24-07

03 39269

AS-1 RED BLOOD CELLS
ADENINE-SALINE ADDED
16.9 mEq Sodium Added
From 500 mL
CPD Whole Blood
Store at 1 to 6 C.

See circular of information for indications, contraindications, cautions and methods of infusion.

VOLUNTEER DONOR
This product may transmit infectious agents. Fx only

PROPERLY IDENTIFY INTENDED RECIPIENT

Baxter Healthcare Corporation
Fenwal Division
Deerfield, IL 60015 USA
07-17-25-629
PL 146 Plastic

Rh POSITIVE

CODE 4R3468
LOT M06K28011

Collected and Processed by
THE BLOOD CENTER
312 South Galvez St.
New Orleans, LA 70119
U.S. License No. 0354
Registration # 2374536

EXPIRES
06/05/07

A
For Autologous Use Only

For Autologous Use Only/Biohazardous
Accurate Blood Center
Anywhere, Worldwide
Registration No. License No.

PROPERLY IDENTIFY INTENDED RECIPIENT
See Cautions of Indications for contraindications, cautions and
methods of injection. This product may transmit infectious agents.
Caution: Federal Law prohibits dispensing without a
prescription

AB
Rh POSITIVE

DIRECTED DONATION

VOLUNTEER DONOR

PLATELETS

From 450 mL CVP Whole Blood
Approximately 45–65 mL

Store at 20 to 24 C

Expiration Date

20 AUG 1997
Donation Identification Number

=α pppppp yy nnnnnnn

=α Data Identifier (incorporates first letter of Country/Center code)

ppppp Uniquely identify collection facility

= K
Donation Identification Number

\[
= \alpha ppppp yy nnnnnn \quad \text{K}
\]

\( = \alpha \) Data Identifier (incorporates first letter of Country/Center code)

ppppp Uniquely identify collection facility
=αppppp yy nnnnnn

- **yy**  Year of Collection
- **nnnnnn**  Donation sequence number
- **ff**  Flag characters or icon
  (00 default in US*)
- **K**  Modulo 36, 37 check character for manual data entry

(*Flag characters used in Europe for “Bag 1 of 2” etc. Currently not used in US)*
- US letters: W or K
- Four digit center code (center may have more than one)
- Year
• Donation sequence number
• Flags (number or icon) (*Flag characters used in Europe for “Bag 1 of 2” etc. Currently defaults to 00 in US)
• Check digit (for manual data entry)
• US letters: W or K
• Four digit center code (center may have more than one)
• Year
• Donation sequence number
• Flags (number or icon)
• Check digit
Expiration Date

- $cyyjjj$
  
  $cyy$ Century and year
  $jjj$ Julian date (day of year)
Expiration Date

$=>cyyjjj$

$=>$ Data identifier

cyy   Century and year

jjj   Julian date (day of year)
Expiration Date & Time

- `&>cyyjjjhhmm`
  
  `&>`  Data identifier for alternative format that includes time
  
  `cyy`  Century and year
  
  `hhmm`  Time represented as hours and minutes (24-hour clock)
Expiration Date: Eye Readable

20 August 2000

15 July 2000 1515
ISBT 128 *Product Code System*

- Describes products in terms of defined component classes, modifiers, attributes
  - Class: Red Cells, Platelets, Plasma (anticoagulant & additive, storage conditions)
  - Modifiers: Washed, Frozen, Thawed, Rejuvenated
  - Attributes: Irradiated, Leukocyte-reduced, Open vs. Closed system, Divided
ISBT 128 *Product Code*

*aooootds*

- Semi-structured, eight character code

```
aaaaaa   product description code
t        type of donation
ds       divisions/splits
```
Product Description Codes

- E0001-zzzzz

- A0000-Dzzzz reserved for internal use; not defined internationally

- Unstructured - no specific meaning associated with the individual characters
Type of Donation

- Sixth position allows for donation type

E0167100

Autologous RED BLOOD CELLS/CPD/from 500 mL whole blood/refrig
Divisions/Splits

E0167000
RED BLOOD CELLS/CPD/from 500 mL whole blood/refrig

E01670A0
RED BLOOD CELLS/CPD/from 500 mL whole blood/refrig/Divided (closed system)

E01670Aa
RED BLOOD CELLS/CPD/from 500 mL whole blood/refrig/Divided (closed system)
Product Description Codes

Codabar

AS-1 RED BLOOD CELLS
Adenine-Saline Added

ISBT 128

RED BLOOD CELLS
ADENINE-SALINE (AS-1) ADDED
<table>
<thead>
<tr>
<th></th>
<th>Codabar</th>
<th>ISBT 128</th>
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<tbody>
<tr>
<td></td>
<td>RED BLOOD CELLS</td>
<td>RED BLOOD CELLS</td>
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<tr>
<td></td>
<td>DEGLYCEROLIZED</td>
<td>DEGLYCEROLIZED</td>
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</table>

*Product Description Codes*
Implementation Steps for Non-Computerized Facilities

- Inform your administration about ISBT
- Revise forms for
  - 13 digit unit number
  - 8 digit product code
- Train nursing staff on labeling changes
  - Location of labeling items
  - Importance of recording all unit # & product code digits
Implementation Steps for Non-Computerized Facilities

- Inform all staff who work in blood bank about ISBT labeling
  - Location of labeling items
  - Importance of recording all 13 digits of unit number
  - Importance of recording all 8 digits of product code
Implementation Steps for Non-Computerized Facilities

• Register with ICCBBA
  – If you modify any products, including platelet pooling
Implementation Steps for Computerized Facilities

- All steps required for non-computerized facilities
- Verify that scanners can read both ISBT and Codabar
- Verify that other equipment can read ISBT labels on tubes
Implementation Steps for Computerized Facilities

- Validate software upgrades that include ISBT
- Obtain lists of ISBT product codes from blood suppliers
- Enter (or assure entrance of) ISBT product codes into computer
Implementation Steps for Computerized Facilities

• Register with ICCBBA
  – If you modify any products, including platelet pooling
Implementation Steps for Computerized Facilities

• Licensed facilities
  – Send in labels to FDA with form 2567 for approval
  – Send in labeling variance (see handout)
<table>
<thead>
<tr>
<th>Codabar</th>
<th>RED BLOOD CELLS DEGLYCEROLIZED</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISBT 128</td>
<td>DEGLYCEROLIZED RED BLOOD CELLS</td>
</tr>
</tbody>
</table>
ICCBBA Website  www.iccbba.org

ISBT 128
More than Identification

Meet the global standard for blood, tissue and organ identification
ISBT 128 sets a global standard for the identification, labeling and information processing of human blood, tissue and organ products across international borders and disparate health care systems. The standard has been designed and perfected over a 12 year period to ensure the highest levels of accuracy, safety and efficiency for the benefit of donors, patients and official ISBT 128 licensed facilities worldwide.

Quick Links

Subscribe to the New ICCBBA Mailing List!

What’s New
Version 3.3.0 of the ISBT 128 product code database is now available to licensed facilities. Updates are listed in the version control sheet. The new database can be downloaded as an Access database or as text file tables.
26 April 2007

Cellular Therapy Reviews - The public comments and STELAB responses for cellular therapy documents are now available. View the comments and documents here.
18 April 2007

Newsletter - The new ICCBBA, Inc. Newsletter has been published. Topics include the proposed changes for the cellular therapy documents, the ICCBBA online subscription mailer, and new ICCBBA

ICCBBA, Inc. enhances safety for patients by managing the ISBT 128 international information standard for use in transfusion and transplantation.
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Password: 

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ICCBBA Website: Licensed User

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Welcome W0671

List Archived Files

Here is a complete listing of files and documents you have access to, sorted by title. You may also sort by date, description, or category by clicking on the column header. Click the title to access that file.

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<td>Barcode Examples: Invalid</td>
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<td>17 Jan 2007</td>
<td>Tool</td>
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<tr>
<td>Barcode Examples: Valid</td>
<td>Valid bar code examples</td>
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<td>Tool</td>
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<td>Check K Quick Calculator</td>
<td>Program that calculates the check character</td>
<td>31 Oct 2005</td>
<td>Tool</td>
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<td>National Representatives</td>
<td>List of National Representatives for requesting new product codes</td>
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<td>Product Code Structure (Blood)</td>
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<td>2. Labels</td>
<td>Technical aspects of printing and verifying bar code labels</td>
<td>30 May 2001</td>
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<td>3. ISBT 128 Blood Product Coding System and new product code request form</td>
<td>30 May 2001</td>
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<td>5. Electronic Data Interchange</td>
<td>Electronic Data Exchange overview</td>
<td>31 May 2001</td>
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<td>7. Case Conversion</td>
<td>CAPS LOCK key toggled on could lead to problems with bar code scanners</td>
<td>29 Jul 2000</td>
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<td>8. Concatenation Issues when &quot;Auto 128&quot; feature is used</td>
<td>29 Jun 2001</td>
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<td>Use of ISBT in higher capacity delivery mechanisms including 2D bar codes, RFID and electronic messages</td>
<td>31 May 2005</td>
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<td>10. Information Data Structures</td>
<td>Manufacturer's information other than containers data structures</td>
<td>29 Jun 2005</td>
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<td>13. US Codebar to ISBT 128 Map</td>
<td>Excel conversion sheet for US Codebar to ISBT 128</td>
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<td>17. US: Labels to be Submitted to FDA</td>
<td>Labels for FDA submission</td>
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# ICCBBA Website: Crosswalk

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<tr>
<th>Codabar Product Code</th>
<th>Codabar Product Name</th>
<th>ISBT 128 Product Barcode</th>
<th>ISBT 128 Divided Code</th>
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</table>
The Blood Center’s ISBT Product List

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
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<tbody>
<tr>
<td>0820</td>
<td>AS-1 RED BLOOD CELLS LEUKOCYTES REDUCED (ACDA anticoagulant)</td>
<td>E4531</td>
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