Introduction to the ISBT 128 Labelling Standard for Blood Components

Hospital Transfusion Service Perspective

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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."

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International Standard

- Global standard introduced in 1994
- 28 countries either implemented or planning implementation

•Denmark	•Austria	•Australia
•Estonia	•Belgium	•Brazil
•Finland	•Canada (Héma-Québec)	•Canada (Canadian Blood Services)
•Iceland	•China	•Germany
•Kuwait	•Egypt	•Israel
•Netherlands	•Portugal	•Japan
•Norway	•Turkey	•Poland
•Singapore	•United States	•Serbia
•Sweden	•United Kingdom	•South Korea
•Switzerland		•Spain

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Regulations / Standards

CSA Standards for Blood and Blood Components

"If bar coding is used, ISBT 128, developed by the International Council of Commonality in Blood Banking Automation should be followed."

AABB Bulletin #05-12 (October 2005)

•*Requires that all AABB accredited blood banks and transfusion services implement ISBT 128 by May 1, 2008.*

•*Several of the larger hospitals in Canada are accredited by AABB and thus are expecting Canadian Blood Services to implement ISBT 128.*

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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

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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

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ISBT 128 Eye Readable Text

ISBT 128 Data Content

Format for barcode data content is defined:

- Donation Number (appppyynnnnnnff)
- Product codes (αooootds)
- Blood group (ggre)
- Date & Time (Julian) (cyyjjjhhmm)
- Special testing
  - General, Red Blood Cells, HLA, Platelet HLA
- Etc……

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Data Identifiers

Data can't be entered into wrong field

- ISBT 128 data structure includes data identifiers that allow software to identify contents of the data and 'validate' that it belongs in the intended field
- For example, blood type cannot be entered into product code field

Allows data to be concatenated

- Allows scan of two adjacent bar codes in one pass

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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

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Codabar Product Codes & Definitions

- 5 digit product codes and definitions do not differentiate donation types
- Product code tables not maintained as new products initiated
- Product codes not standardized between countries, blood agencies

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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.

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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

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Product Codes – Codabar vs ISBT 128

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

Codabar Product Code	00150

ISBT 128 Product Codes include:	
Whole Blood |CPD/450mL/refg	E0009
Whole Blood |CPD/450mL/refg/Open	E0013
Whole Blood |CPD/500mL/refg	E0023
Whole Blood |CPD/500mL/refg/Open	E0027

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Unique Donation Number

- Current donation numbers are not unique
  - Look back - traceability
  - Consolidation of laboratories
  - Hospital lab systems will not allow entry of a duplicate donation number
- At Canadian Blood Services donation numbers repeat every year
  - *Some hospitals have reported duplicate donation numbers on components received*
  - *Manual entry and workarounds increase risk of error*

ISBT 128 Donation Number

- 13 Digit ISBT 128 Donation Number provides unique identification of blood products world wide for a 100 year period
- Eliminates need to re-number units of blood
- Supports centralized donor testing

ISBT 128 Donation Number

C0500 07 123456 21 Q

- 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

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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

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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

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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
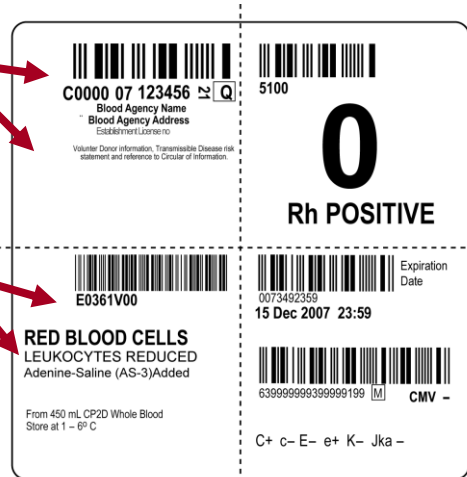
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Standard ISBT 128 End Label Format
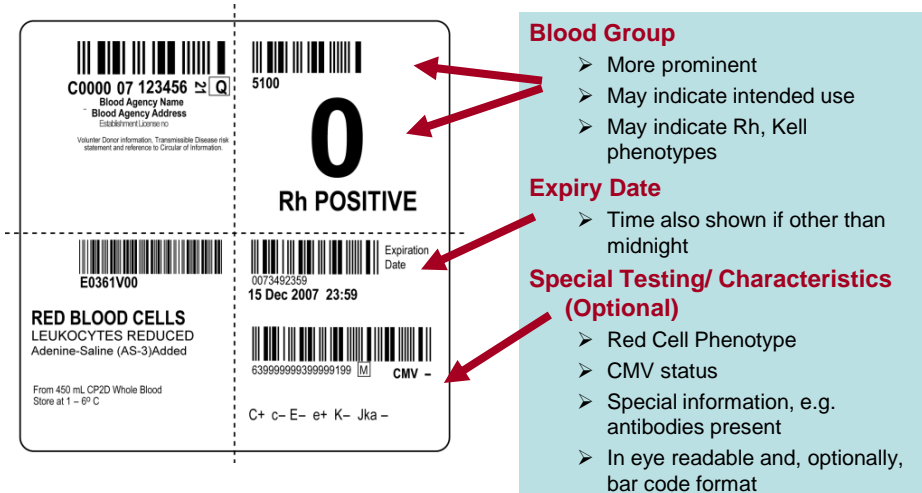
Unique Donation Number & Static Text

- 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)

C0000 07 123456 21 Q 5100
Blood Agency Name
Blood Agency Address
Establishment License no

Volunteer Donor Information, Transmissible Disease risk
statement and reference to Circular of Information.

0
Rh POSITIVE

E0361V00

Expiration Date
0073492359
15 Dec 2007 23:59

RED BLOOD CELLS
LEUKOCYTES REDUCED
Adenine-Saline (AS-3)Added

From 450 mL CP2D Whole Blood
Store at 1 – 6º C

6399999993999199 M CMV –

C+ c– E– e+ K– Jka –

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Standard ISBT 128 End Label Format

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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

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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

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)

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

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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

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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

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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

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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

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SHARE YOUR HEALTH AND VITALITY WITH SOMEONE IN NEED

For more information on ISBT 128 implementation at Canadian Blood Services:

www.transfusionmedicine.ca

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