

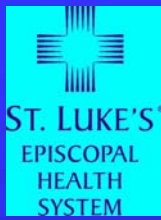


ISBT 128-A Hospital Blood Center Perspective

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Hospital Blood Center Perspective

- St. Luke's Episcopal Hospital is a 950 bed tertiary care hospital in the Texas Medical Center in Houston.
- Home of the Texas Heart Institute
- Primary teaching hospital for Baylor College of Medicine.
- Emphasis on Cardiovascular Care

ISBT 128 Implementation

- SLEH Blood Center collects and labels 60,000 ISBT blood products annually.
- SLEH Transfusion Service transfuses 75,000 blood products annually.
- SLEH was uniquely positioned to implement ISBT because all of our blood products are used internally.
 - ◆ We are not FDA licensed to ship out of state.
- All of our donor testing is done by the Gulf Coast Regional Blood Center.

ISBT 128 Implementation

- With installation of our Wyndgate Safetrace Donor system in 2002 we converted to ISBT labeling on all of the products we produce.
- With installation of our Safetrace TX system in July 2004 we converted to ISBT labeling for all modified ISBT products for transfusion.
- July 2004- First vein-to-vein ISBT 128 products were issued with electronic crossmatch.

21 CFR 606.121 c (13)

FDA Final Ruling

- Effective April 26, 2006, each label must have machine-readable information that contains, at a minimum:
 - ◆ (A) A unique facility identifier;
 - ◆ (B) Lot number relating to the donor;
 - ◆ (C) Product code; and
 - ◆ (D) ABO and Rh of the donor.
- Expiration Date/time barcode is not required but may be necessary for your software when doing label validation or issuing. Julian date will be expected by software for ISBT units.

AABB Accreditation

- Must have a written plan in place to implement ISBT by May 2008.
 - ◆ 25th Edition of the Standards

ICCBBA Registration

- ◆ 1 Registration per system under the same corporate umbrella with same billing address.
- ◆ Separate Facility Identification Number (FIN) for every facility that applies ISBT labels.
- ◆ Annual license fee to use the coding structure.
- ◆ Source for sample barcodes to use for validation
- ◆ Program to search for the barcode you need.
- ◆ Forms to request new product codes
- ◆ Ongoing maintenance of ISBT 128 for tissue and cells.

ICCBBA Website New Documents

- ◆ Product Code Database v 3.1.0
 - ☞ 100 new product codes
- ◆ Product Coding: Bounded Lists and Definitions v3.1.0
 - ☞ Include classes, modifiers, attributes which can be used to search the database.
- ◆ Product Code Structure (Blood Components) v2.0.0
- ◆ Product Code Structure-Cellular Therapy v2.0.0
- ◆ Frequently asked questions- great resource

Where to begin?

- Ask software vendor for guidance adding ISBT product codes to system tables.
- Identify and list ISBT product codes for every product you manufacture or modify.
- Develop your validation plan.
- Request a variance from FDA for ISBT labeling
 - ◆ Due to anticoagulant appearing below the product name.

Hardware Evaluation

- Test your scanners ability to scan every field in every screen.
 - ◆ New scanners may be needed that read both Codabar and ISBT.
 - ◆ Scanners must not convert case.
- Find our from your software vendor what printers are validated with your software.
 - ◆ Printer must be 300 dpi.
 - ◆ Must have firmware to print ISBT 128 label
 - ◆ Or purchase preprinted ISBT labels if low volume.

Blood Center Validation

- Include all steps in your process and refine plan as needed.
 - ◆ Registering donor with ISBT unit number
 - ◆ Component preparation
 - ◆ Entering testing results
 - ◆ Instrument testing
 - ◆ Label printing
 - ◆ Label validation
 - ◆ Component shipping
 - ◆ Component importing



Blood Center Implementation Issues

- Obtain ISBT unit number sets.
- Obtain software to format ISBT labels.
- Obtain printers with 300 dpi printhead and firmware to print ISBT.
- Insure donor testing site can test on ISBT unit numbers. If not, identify solution.
- If doing testing internally make sure all instruments can read ISBT barcodes on testing tubes.
- Determine whether instruments can discriminate if testing both Codabar and ISBT on same batch.



Blood Center Implementation Issues

- Obtain plasma boxes with opening big enough to apply 4X4 label.
- Insure forms and reports have sufficient space for 13 character unit number.
- Create templates with product barcodes to scan during component manufacturing.
- Notify customers and provide sample labels for system validation.
- Submit labels to FDA for approval if products are licensed.

Transfusion Service Validation

Include all steps in your process and refine plan as needed.

- ◆ Component shipping/importing
- ◆ Component modification (pooling, thawing, irradiation, leukoreduction)
- ◆ Modified label printing
- ◆ Modified label validation
- ◆ Product ID Tag print
- ◆ Component issue
- ◆ Component billing



Transfusion Service Implementation Issues

- Registration with ICBBA is required if you apply ISBT 128 labels.
 - ◆ Pool - new ISBT pool number required
 - ◆ Aliquot
 - ◆ Irradiate or Leukoreduce
 - ◆ Thaw FFP- if not transfused within 24 hrs must be relabeled as plasma.
- Plan for modified product labeling. (preprinted labels or on demand printers and software.)
- Plan for labeling during system downtime.
- Obtain labels for validation from suppliers.
- Notify nursing that unit numbers will be longer and check that infusion records have space.

Pooling Platelets

- New donor identification number (DIN) is required.
- Pooling facility appears in upper left quadrant where the collection facility usually appears.

Modified Labels

- Leukoreduction or irradiation of products from another facility requires the modifying facility and FDA registration number and US License number to appear in the lower right quadrant on the label.
- The collection facility and FDA registration number and US License number appears in the upper left quadrant.

ISBT 128 Quality Improvements

- Complying with the ISBT 128 standard ensured that multiple vendor's software worked together without customization.
- Ability to scan every field every time.
 - ◆ ISBT 128 data structures clearly define each field.

ISBT 128 Quality Improvements

- Better tracking by unit, product, and collection facility due to unique unit numbers.
- No possibility of running out of unit numbers or duplicating another collection facility.

ISBT Unit Number (BUI)

W044604123456 **K**

- Country Code (W for USA)
- 4 Digit Collection Facility ID
- 2 Digit Year of Collection
- 6 Digit Unit Serial Number (999,999 units)
- Calculated Check Digit
 - ◆ Calculated on the 13 Character BUI
 - ◆ Supports Accurate Manual Data Entry
 - ◆ Non-data Character (Not in Barcode)

ISBT Expiration Date

Gregorian vs. Julian

(Eye-readable vs. Barcode)

12/24/2001 vs. 001358
=> cyyjjj

- ◆ => ISBT Data Identifier
- ◆ c Century (2000 - 2099)
- ◆ yy Year (2001 - 2099)
- ◆ jjj Julian Date (001 - 365)

ISBT 128 Quality Improvements

- Better tracking of multiple products collected by apheresis due to unique product codes. (Platelet co-components, double RBC).
 - ◆ Type of donation- volunteer or paid is required
 - ◆ Type of donation- autologous, directed, is not required but helpful.
 - ◆ O default is not allowed by FDA on transfusable products.

ISBT Product Barcode

= < E0000 t d s

- ◆ = < ISBT Data Identifier
- ◆ E0000 ISBT Assigned Product Code
- ◆ t Donation Code
- ◆ d Division of Primary Product
- ◆ s Split of a Division

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ISBT Product Barcode

= < E0000tds

- ◆ E0332 LR IRR RBC
- ◆ E0332V LR IRR RBC Volunteer
- ◆ E0332V00 LR IRR RBC Volunteer
Undivided/No Split
- ◆ E00332VA0 LR IRR RBC Volunteer
1 Division/No Split
- ◆ E00332VAa LR IRR RBC Volunteer
1 Division/1 Split

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ISBT 128 Quality Improvements

- Platelet and RBC donation

E3087V00 Apheresis platelets product#1

E3088V00 Apheresis platelets product#2

E0605V00 Apheresis RBC

ISBT 128 Quality Improvements

- Platelet and Plasma donation

E3077V00 Apheresis platelet–single product

E1613V00 Apheresis plasma 400-600ml

ISBT 128 Quality Improvements

- Directed double RBC donation

E0693D00 Apheresis RBC product#1

E0694D00 Apheresis RBC product#2

ISBT 128 Quality Improvements

- RBC donation type

E0195A00 CPD-A1 RBC- Autologous

E0195D00 CPD-A1 RBC- Directed

E0195V00 CPD-A1 RBC- Allogeneic

ISBT 128 Quality Improvements

- Better inventory management of autologous and directed products.
 - ◆ Type of donation included in product code.
 - ◆ Intended use included in ABO/RH.
 - ☞ If directed is to be crossed over it should not be encoded in the ABO/RH. Use Not Specified - Allogeneic.
 - ◆ Apheresis is now a modifier and not part of component class and should appear above the product class on the label. US v2.0

ISBT Blood Group Barcode

=% **gg**re

- ◆ =% ISBT Data Identifier
- ◆ **gg** **ABO/Rh** + **Intended Use**
- ◆ **r** **Kell / Rh / Miltenberger Phenotype**
(Not Used In US)
- ◆ **e** Future Use by ICCBBA

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ISBT Blood Groups

=% **ggre**

- ◆ 9700 O NEG Autologous Use Only
- ◆ 9800 O NEG Autologous Only Biohazard
- ◆ 9500 O NEG Not Specified (Allogeneic)
- ◆ 9100 O NEG Directed Only
- ◆ 5100 O POS Not Specified (Allogeneic)
- ◆ 6200 A POS Not Specified (Allogeneic)
- ◆ 8400 AB POS Not Specified
(Allogeneic)

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ISBT 128 Quality Improvements

- Label for products modified in Transfusion Service much improved.
 - ◆ 4X4 full face label can be printed for every product.
 - ◆ Label validation software insures correct label.
 - ◆ Compare printer cost vs preprinted label cost.

- Codabar Platelets can be pooled and assigned ISBT pool number and relabeled as ISBT product with full face label.
 - ◆ This may be software dependent.

ISP RAD-SURE[®] OPERATOR: YS DATE: 8/10/04
25 Gy INDICATOR [redacted] IRRADIATED
ISP TECHNOLOGIES INC. LOT NO: M13611U25 EXP:9/05

8221212
[barcode]

CPDA-1 RED BLOOD CELLS
IRRADIATED

From 450 mL CPDA-1 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.
Rx ONLY
PROPERLY IDENTIFY INTENDED RECIPIENT

Manufactured by:
TERUMO CORPORATION
Tokyo, Japan
LOT NO.: 040412GY
TERUFLEX[®] CODE: BB* TCD456A

EXPIRES 9/10/04 YS 9/11/04
[barcode] 01/10/04
Negative by FDA License test for Anti-HIV. Non Reactive for HBsAg & Syphilis by an FDA required test. No unexpected antibodies detected.
A
Rh NEGATIVE

BLOOD BANK
ST. LUKE'S EPISCOPAL HOSPITAL
6720 Bertner Avenue
Houston, Texas 77030
832-355-4116
[barcode]
Registration #1672092

TRIPLE BLOOD BAG

ISP RAD-SURE[®] OPERATOR: YS DATE: 8/10/04
25 Gy INDICATOR [redacted] IRRADIATED
ISP TECHNOLOGIES INC. LOT NO: M13611U25 EXP:9/05

[barcode]
W0562 04 010302 4

ST LUKE'S EPISCOPAL HOSP
HOUSTON, TX 77030
Reg. No. 1672092

PROPERLY IDENTIFY INTENDED RECIPIENT
See Circular of Information for Indications, contraindications, cautions and methods of infusion. This product may transmit infectious agents.
Rx ONLY.

VOLUNTEER DONOR

[barcode]
E0206V00

RED BLOOD CELLS
IRRADIATED
From 450 mL CPDA-1 Whole Blood.
Store at 1 to 6°C.

[barcode] 0600
A
Rh NEGATIVE

[barcode] 0442512359
Expiration Date
07 SEP 2004 23:59

ST LUKE'S EPISCOPAL HOSP
HOUSTON, TX 77030
Registration No. 1672092

ISBT 128 Quality Improvements

- Eliminated preprinted codabar product labels and handwritten expiration dates.
 - ◆ Now used for remaining Codabar products only.

ISBT 128 Quality Improvements

- Standardization in ISBT 128 barcode labels enable software applications to be written to check product and patient identification prior to administration to prevent errors.
 - ◆ One application has already received 510K clearance. We have installed Care Fusion BloodCare.
 - ◆ Allows software safety checks to extend from blood donation to patient transfusion.

References

- AABB Website
- FDA Website
 - ◆ www.fda.gov- Guidelines for Industry- Bar Code Label requirements.
- ICCBBA Web Site
 - ◆ www.aabb.org-AABB ISBT Implementation Plan
 - ◆ www.iccbba.com
 - ◆ Complete List of ISBT 128 Product Code
 - ◆ US Industry Consensus Standard for Uniform Labeling of Blood & Blood Components
 - ◆ Membership Information